UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA

In Re: Actos (Pioglitazone) Products Liability Litigation	
	6:11-md-2299
This Document Applies to: Charles Ranaudo, et al., v. Takeda Pharmaceuticals America, Inc., et al., Case No. 6:13-cv-00880-RFD-PJH ***see Attachment 1**	**JUDGE DOHERTY**
	MAGISTRATE JUDGE HANNA

DEFENDANTS' ANSWER AND SEPARATE OR AFFIRMATIVE DEFENSES TO PLAINTIFFS' COMPLAINT

Takeda Pharmaceuticals America, Inc. ("TPA"), Takeda Pharmaceuticals U.S.A., Inc. ("TPUSA"), Takeda Pharmaceutical Company Limited ("TPC") (collectively "Takeda"), and Eli Lilly and Company ("Eli Lilly"), by and through their attorneys, answer Plaintiffs' Complaint as follows:

INTRODUCTION

1. This is an action for personal injury, and in certain cases wrongful death, on behalf of Plaintiffs/Decedents and loss of consortium on behalf of Plaintiffs' spouses against Defendants who were responsible for the prescription drug Actos and/or Actosplus Met, Actosplus Met XR, Duetact (Actos), a diabetes medication used by the injured Plaintiffs, as set forth below, that proximately caused the Plaintiffs to sustain injuries and damages.

ANSWER: Takeda and Eli Lilly admit that Plaintiffs, through their counsel of record, have filed an action against the named defendants. Takeda and Eli Lilly also admit that ACTOS® (pioglitazone HCl) is a prescription medication approved by the FDA for prescription by licensed physicians as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus and that, pursuant to approval by the FDA, pioglitazone HCl is marketed

for prescription by licensed physicians in the United States as ACTOS®, in combination with metformin as ACTOplus Met® and ACTOplus Met XR®, and in combination with glimepiride as Duetact®. Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' use of ACTOS® and medical diagnoses.

Takeda further admits that, pursuant to approval by the FDA, TPC has researched and manufactured ACTOS®, TPA has sold, marketed and distributed ACTOS®, Eli Lilly marketed ACTOS® from 1999 to 2006, and TPUSA has marketed ACTOS® for prescription by licensed physicians in the United States. Takeda denies the remaining allegations of paragraph 1.

Eli Lilly admits that, pursuant to approval by the FDA, it marketed ACTOS® from 1999 to 2006 for prescription by licensed physicians in the United States. Eli Lilly further admits, on information and belief, that, pursuant to approval by the FDA, TPC has manufactured ACTOS®, TPA has sold, marketed and distributed ACTOS®, and TPUSA has marketed ACTOS® for prescription by licensed physicians in the United States. Eli Lilly denies the remaining allegations of paragraph 1.

STATEMENT OF JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiffs exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiffs reside.

ANSWER: Takeda and Eli Lilly state that the allegations of paragraph 2 constitute legal conclusions to which no response is required. To the extent that the allegations of paragraph 2 are construed as factual allegations directed to Takeda and Eli Lilly, they admit that the amount in controversy exceeds $75,000 exclusive of interest and costs, and that this Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a)(1).

Takeda further admits that TPA and TPUSA are Delaware corporations with their principal places of business in Deerfield, Illinois, that TPC is a Japanese corporation with its principal place of business in Osaka, Japan, and, on information and belief, that Eli Lilly is an Indiana corporation with its principal place of business in Indianapolis, Indiana. Takeda lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 2.

Eli Lilly further admits that it is an Indiana corporation with its principal place of business in Indianapolis, Indiana, and, on information and belief, that TPA is a Delaware corporation with its principal place of business in Illinois. Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 2.

3. Venue of this case is appropriate in the United States District Court for the Western District of Louisiana pursuant to 28 U.S.C. § 1391 and General Order No. 1. Plaintiffs state that, but for the Order permitting direct filing into the Western District of Louisiana pursuant to the First General Order, plaintiffs would have filed their cases in the United States District Courts encompassing their residence. Therefore, Plaintiffs respectfully request that at the time of transfer of this action back to the trial court for further proceedings that their cases be transferred to the referenced District Court.

ANSWER: Takeda and Eli Lilly state that the allegations of paragraph 3 constitute legal conclusions to which no response is required. To the extent that the allegations of paragraph 3 are construed as factual allegations directed to Takeda and Eli Lilly, they admit that the First General Order dated January 23, 2012 states that counsel may "file directly within the Western District of Louisiana . . . a case anticipated to be deemed Related to MDL 6:11-md-2299 ACTOS (Pioglitazone) Products Liability Litigation . . . ." and that transfer to a place of proper venue for trial is appropriate at a future time. Takeda and Eli Lilly deny any remaining or inconsistent allegations of paragraph 3.

PARTIES

PLAINTIFFS/DECEDENTS

4.1 Plaintiff, CHARLES RANAUDO, allege [sic] as follows:

a. Plaintiff, CHARLES RANAUDO, is a citizen of Florida.

b. Upon information and belief, plaintiff, CHARLES RANAUDO, ingested Actos on or before January 4, 2008 through on or after November 9, 2009.

c. Following and as a legal and proximate result of Actos use, plaintiff, CHARLES RANAUDO, suffered bladder cancer on or about November 9, 2009.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff Charles Ranaudo's citizenship, ingestion of ACTOS®, and medical diagnosis. Takeda and Eli Lilly deny that ACTOS® causes bladder cancer and further deny the remaining allegations of paragraph 4.1, including all subparts.

4.2 Plaintiffs, GENE STEINLEY and JEAN MARIE STEINLEY, allege as follows:

a. Plaintiffs, GENE STEINLEY and JEAN MARIE STEINLEY, are citizens of South Dakota.

b. Upon information and belief, plaintiff, GENE STEINLEY, ingested Actos on or before January 2009 through on or after May 6, 2011.

c. Following and as a legal and proximate result of Actos use, plaintiff, GENE STEINLEY, suffered bladder cancer on or about May 6, 2009.

d. Plaintiff, JEAN MARIE STEINLEY, was and is the lawful spouse of plaintiff, GENE STEINLEY, and as such, was and is entitled to the comfort, enjoyment, society and services of her spouse.

e. Plaintiff, JEAN MARIE STEINLEY's, loss of consortium claims are alleged in the Fifteenth Cause of Action.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs Gene Steinley and Jean Marie Steinley's citizenship and marital status and Plaintiff Gene Steinley's ingestion of ACTOS® and medical diagnosis. Takeda and Eli Lilly deny that ACTOS® causes bladder cancer and further deny the

remaining allegations of paragraph 4.2, including all subparts.

4.3 Plaintiffs, JAMES W. TOMPKINS and LYDIA B. TOMPKINS, allege as follows:

a. Plaintiffs, JAMES W. TOMPKINS and LYDIA B. TOMPKINS, are citizens of Washington.

b. Upon information and belief, plaintiff, JAMES W. TOMPKINS, ingested Actos on or before May 17, 2008 through on or after November 10, 2010.

c. Following and as a legal and proximate result of Actos use, plaintiff, JAMES W. TOMPKINS, suffered bladder cancer on or about November 10, 2010.

d. Plaintiff, LYDIA B. TOMPKINS, was and is the lawful spouse of plaintiff, JAMES W. TOMPKINS, and as such, was and is entitled to the comfort, enjoyment, society and services of her spouse.

e. Plaintiff, LYDIA B. TOMPKINS's, loss of consortium claims are alleged in the Fifteenth Cause of Action.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs James W. Tompkins and Lydia B. Tompkin's citizenship and marital status and Plaintiff James W. Tompkins's ingestion of ACTOS® and medical diagnosis. Takeda and Eli Lilly deny that ACTOS® causes bladder cancer and further deny the remaining allegations of paragraph 4.3, including all subparts.

4.4 Plaintiffs, ROBERT WILLIAM WAGNER and BARBARA J. WAGNER, allege as follows:

a. Plaintiffs, ROBERT WILLIAM WAGNER and BARBARA J. WAGNER, are citizens of Florida.

b. Upon information and belief, plaintiff, ROBERT WILLIAM WAGNER, ingested Actos on or before 2001 through on or after June 2006.

c. Following and as a legal and proximate result of Actos use, plaintiff, ROBERT WILLIAM WAGNER, suffered bladder cancer on or about June 2006.

d. Plaintiff, BARBARA J. WAGNER, was and is the lawful spouse of plaintiff, ROBERT WILLIAM WAGNER, and as such, was and is entitled to the comfort, enjoyment, society and services of her spouse.

e. Plaintiff, BARBARA J. WAGNER's, loss of consortium claims are alleged in the Fifteenth Cause of Action.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs Robert William Wagner and Barbara J. Wagner's citizenship and marital status and Plaintiff Robert William Wagner's ingestion of ACTOS® and medical diagnosis. Takeda and Eli Lilly deny that ACTOS® causes bladder cancer and further deny the remaining allegations of paragraph 4.4, including all subparts.

DEFENDANTS

5. Takeda Pharmaceuticals America, Inc. is a Delaware Corporation which has its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

ANSWER: Takeda admits that TPA is a Delaware corporation with its principal place of business in Deerfield, Illinois.

Eli Lilly states that the allegations of paragraph 5 do not state any allegations as to Eli Lilly and, therefore, no response by Eli Lilly is required. If a response is required, Eli Lilly admits, on information and belief, that TPA is a Delaware corporation with its principal place of business in Deerfield, Illinois.

6. Takeda Pharmaceuticals America, Inc. is a wholly owned subsidiary of Takeda Pharmaceuticals USA, Inc. f/k/a Takeda Pharmaceuticals North America, Inc.

ANSWER: Takeda admits that TPA is a wholly-owned subsidiary of TPUSA.

Eli Lilly states that the allegations of paragraph 6 do not state any allegations as to Eli Lilly and, therefore, no response by Eli Lilly is required. If a response is required, Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 6.

7. Takeda Pharmaceuticals America, Inc. has transacted and conducted business within the States of Florida, South Dakota and Washington.

ANSWER: Takeda admits that, pursuant to approval by the FDA, TPA sells, markets, and distributes ACTOS® for prescription by licensed physicians in the United States, including the States of Florida, South Dakota and Washington. Takeda denies the remaining allegations of paragraph 7.

Eli Lilly states that the allegations of paragraph 7 do not state any allegations as to Eli Lilly and, therefore, no response by Eli Lilly is required. If a response is required, Eli Lilly admits, on information and belief, that, pursuant to approval by the FDA, TPA sells, markets, and distributes ACTOS® for prescription by licensed physicians in the United States, including the States of Florida, South Dakota and Washington. Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 7.

8. Takeda Pharmaceuticals America, Inc. has derived substantial revenue from goods and products used in the States of Florida, South Dakota and Washington.

ANSWER: Takeda admits that, pursuant to approval by the FDA, TPA sells, markets, and distributes ACTOS® for prescription by licensed physicians in the United States, including the States of Florida, South Dakota and Washington, and that TPA has received revenue from the sale ACTOS® in the United States, including the States of Florida, South Dakota and Washington. Takeda states that the phrase "substantial revenue" is vague and ambiguous. Accordingly, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 8 pertaining to same. Takeda denies the remaining allegations of paragraph 8.

Eli Lilly states that the allegations of paragraph 8 do not state any allegations as to Eli Lilly and, therefore, no response by Eli Lilly is required. If a response is required, Eli Lilly admits, on information and belief, that, pursuant to approval by the FDA, TPA sells, markets, and distributes ACTOS® for prescription by licensed physicians in the United States, including

the States of Florida, South Dakota and Washington. Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 8.

9. Takeda Pharmaceuticals America, Inc. expected or should have expected their acts to have consequences within the States of Florida, South Dakota and Washington, and derived substantial revenue from interstate commerce.

ANSWER: Takeda states that the phrases "their acts," "consequences," and "substantial revenue" are vague and ambiguous. Accordingly, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 9 pertaining to same. Takeda denies the remaining allegations of paragraph 9.

Eli Lilly states that the allegations of paragraph 9 do not state any allegations as to Eli Lilly and, therefore, no response by Eli Lilly is required. If a response is required, Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 9.

10. Takeda Pharmaceuticals USA, Inc. f/k/a Takeda Pharmaceuticals North America, Inc. is a Delaware corporation which has its principal place of business at One Takeda Parkway Deerfield, IL 60015.

ANSWER: Takeda admits that TPUSA is a Delaware corporation with its principal place of business in Deerfield, Illinois.

Eli Lilly states that the allegations of paragraph 10 do not state any allegations as to Eli Lilly and, therefore, no response by Eli Lilly is required. If a response is required, Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 10.

11. Takeda Pharmaceuticals USA, Inc. f/k/a Takeda Pharmaceuticals North America, Inc. is a wholly owned subsidiary of Takeda Pharmaceutical Company Limited.

ANSWER: Takeda admits that TPUSA is a wholly-owned subsidiary of TPC.

Eli Lilly states that the allegations of paragraph 11 do not state any allegations as to Eli Lilly and, therefore, no response by Eli Lilly is required. If a response is required, Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 11.

12. Takeda Pharmaceuticals USA, Inc. f/k/a Takeda Pharmaceuticals North America, Inc. has transacted and conducted business within the States of Florida, South Dakota and Washington.

ANSWER: Takeda admits that, pursuant to approval by the FDA, TPUSA markets ACTOS® for prescription by licensed physicians in the United States, including the States of Florida, South Dakota and Washington. Takeda denies the remaining allegations of paragraph 12.

Eli Lilly states that the allegations of paragraph 12 do not state any allegations as to Eli Lilly and, therefore, no response by Eli Lilly is required. If a response is required, Eli Lilly admits, on information and belief, that, pursuant to approval by the FDA, TPUSA markets ACTOS® for prescription by licensed physicians in the United States, including the States of Florida, South Dakota and Washington. Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 12.

13. Takeda Pharmaceuticals USA, Inc. f/k/a Takeda Pharmaceuticals North America, Inc. has derived substantial revenue from goods and products used in the States of Florida, South Dakota and Washington.

ANSWER: Takeda admits that, pursuant to approval by the FDA, TPUSA markets ACTOS® for prescription by licensed physicians in the United States, including the States of Florida, South Dakota and Washington, and that TPUSA has received revenue from the sale ACTOS® in the United States, including the States of Florida, South Dakota and Washington. Takeda states that the phrase "substantial revenue" is vague and ambiguous. Accordingly, Takeda lacks knowledge

or information sufficient to form a belief as to the truth of the allegations of paragraph 13 pertaining to same. Takeda denies the remaining allegations of paragraph 13.

Eli Lilly states that the allegations of paragraph 13 do not state any allegations as to Eli Lilly and, therefore, no response by Eli Lilly is required. If a response is required, Eli Lilly admits, on information and belief, that, pursuant to approval by the FDA, TPUSA markets ACTOS® for prescription by licensed physicians in the United States, including the States of Florida, South Dakota and Washington. Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 13.

14. Takeda Pharmaceuticals USA, Inc. f/k/a Takeda Pharmaceuticals North America, Inc. expected or should have expected their acts to have consequences within the States of Florida, South Dakota and Washington, and derived substantial revenue from interstate commerce.

ANSWER: Takeda states that the phrases "their acts," "consequences," and "substantial revenue" are vague and ambiguous. Accordingly, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 14 pertaining to same. Takeda denies the remaining allegations of paragraph 14.

Eli Lilly states that the allegations of paragraph 14 do not state any allegations as to Eli Lilly and, therefore, no response by Eli Lilly is required. If a response is required, Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 14.

15. Takeda Pharmaceutical Company Limited is a foreign corporation with its principal place of business located at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, 540-8645, Japan.

ANSWER: Takeda admits that TPC is a Japanese corporation with its principal place of business in Osaka, Japan.

Eli Lilly states that the allegations of paragraph 15 do not state any allegations as to Eli Lilly and, therefore, no response by Eli Lilly is required. If a response is required, Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 15.

16. Takeda Pharmaceutical Company Limited is the parent company of Takeda Pharmaceuticals USA, Inc. f/k/a Takeda Pharmaceuticals North America, Inc., and Takeda Pharmaceuticals America, Inc. is a wholly-owned subsidiary of Takeda Pharmaceuticals USA, Inc. f/k/ a Takeda Pharmaceuticals North America, Inc.

ANSWER: Takeda admits that TPC is the parent company of TPUSA and that TPA is a wholly-owned subsidiary of TPUSA.

Eli Lilly states that the allegations of paragraph 16 do not state any allegations as to Eli Lilly and, therefore, no response by Eli Lilly is required. If a response is required, Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 16.

17. Takeda Pharmaceutical Company Limited has transacted and conducted business within the States of Florida, South Dakota and Washington.

ANSWER: Takeda denies the allegations of paragraph 17.

Eli Lilly states that the allegations of paragraph 17 do not state any allegations as to Eli Lilly and, therefore, no response by Eli Lilly is required. If a response is required, Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 17.

18. Takeda Pharmaceutical Company Limited has derived substantial revenue from goods and products used in the States of Florida, South Dakota and Washington.

ANSWER: Takeda admits that TPC has received revenue from the sale ACTOS® in the United States, including the States of Florida, South Dakota and Washington. Takeda states that the phrase "substantial revenue" is vague and ambiguous. Accordingly, Takeda lacks knowledge

or information sufficient to form a belief as to the truth of the allegations of paragraph 18 pertaining to same. Takeda denies the remaining allegations of paragraph 18.

Eli Lilly states that the allegations of paragraph 18 do not state any allegations as to Eli Lilly and, therefore, no response by Eli Lilly is required. If a response is required, Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 18.

19. Takeda Pharmaceutical Company Limited expected or should have expected their acts to have consequences within the States of Florida, South Dakota and Washington, and derived substantial revenue from interstate commerce.

ANSWER: Takeda states that the phrases "their acts," "consequences," and "substantial revenue" are vague and ambiguous. Accordingly, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 19 pertaining to same. Takeda denies the remaining allegations of paragraph 19.

Eli Lilly states that the allegations of paragraph 19 do not state any allegations as to Eli Lilly and, therefore, no response by Eli Lilly is required. If a response is required, Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 19.

20. Eli Lilly and Company [hereinafter "Lilly"] is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285.

ANSWER: Eli Lilly admits that it is an Indiana corporation with its principal place of business in Indianapolis, Indiana.

Takeda states that the allegations of paragraph 20 do not state any allegations as to Takeda and, therefore, no response by Takeda is required. If a response is required, Takeda admits, on information and belief, that Eli Lilly is an Indiana corporation with its principal place of business in Indianapolis, Indiana.

21. Lilly has transacted and conducted business within the States of Florida, South Dakota and Washington.

ANSWER: Eli Lilly admits that, pursuant to approval by the FDA, it marketed ACTOS® from 1999 to 2006 for prescription by licensed physicians in the United States, including the States of Florida, South Dakota and Washington. Eli Lilly denies the remaining allegations of paragraph 21.

Takeda states that the allegations of paragraph 21 do not state any allegations as to Takeda and, therefore, no response by Takeda is required. If a response is required, Takeda admits that, pursuant to approval by the FDA, Eli Lilly marketed ACTOS® from 1999 to 2006 for prescription by licensed physicians in the United States, including the States of Florida, South Dakota and Washington. Takeda lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 21.

22. Lilly has derived substantial revenue from goods and products used in the States of Florida, South Dakota and Washington.

ANSWER: Eli Lilly admits that, pursuant to approval by the FDA, it marketed ACTOS® from 1999 to 2006 for prescription by licensed physicians in the United States, including the States of Florida, South Dakota and Washington, and that it has received revenue from the sale of ACTOS® in the United States, including the States of Florida, South Dakota and Washington. Eli Lilly states that the phrase "substantial revenue" is vague and ambiguous. Accordingly, Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 22 pertaining to same. Eli Lilly denies the remaining allegations of paragraph 22.

Takeda states that the allegations of paragraph 22 do not state any allegations as to Takeda and, therefore, no response by Takeda is required. If a response is required, Takeda admits that, pursuant to approval by the FDA, Eli Lilly marketed ACTOS® from 1999 to 2006

for prescription by licensed physicians in the United States, including the States of Florida, South Dakota and Washington, and, on information and belief, that Eli Lilly has received revenue from the sale of ACTOS® in the United States, including the States of Florida, South Dakota and Washington. Takeda states that the phrase "substantial revenue" is vague and ambiguous. Accordingly, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 22 pertaining to same. Takeda lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 22.

23. Lilly expected or should have expected their acts to have consequences within the States of Florida, South Dakota and Washington, and derived substantial revenue from interstate commerce.

ANSWER: Eli Lilly states that the phrases "their acts," "consequences," and "substantial revenue" are vague and ambiguous. Accordingly, Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 23 pertaining to same. Eli Lilly denies the remaining allegations of paragraph 23.

Takeda states that the allegations of paragraph 23 do not state any allegations as to Takeda and, therefore, no response by Takeda is required. If a response is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 23.

FACTUAL BACKGROUND

24. Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted and sold ACTOS, for the treatment of type two diabetes mellitus.

ANSWER: Takeda admits that, pursuant to approval by the FDA, TPC has manufactured ACTOS®, TPA has sold, marketed and distributed ACTOS®, Eli Lilly marketed ACTOS® from 1999 to 2006, and TPUSA has marketed ACTOS® for prescription by licensed physicians in the

United States as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Takeda denies the remaining allegations of paragraph 24.

Eli Lilly admits that, pursuant to approval by the FDA, it marketed ACTOS® from 1999 to 2006 for prescription by licensed physicians in the United States as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Eli Lilly also admits, on information and belief, that, pursuant to approval by the FDA, TPC manufactures ACTOS®, TPUSA markets ACTOS®, and TPA sells, markets, and distributes ACTOS® for prescription by licensed physicians in the United States as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 24. Eli Lilly specifically denies any allegation that it designed or manufactured ACTOS®.

25. ACTOS was jointly launched by Takeda Pharmaceuticals USA, Inc. f/k/a Takeda Pharmaceuticals North America, Inc. and Lilly in 1999.

ANSWER: Takeda and Eli Lilly admit that the FDA approved ACTOS® for marketing in the United States in 1999 and that ACTOS® was marketed in the United States pursuant to a co-promotion agreement between TPUSA and Eli Lilly from 1999 to March 31, 2006. Takeda and Eli Lilly deny any remaining allegations of paragraph 25.

26. On April 20, 2006, Takeda Pharmaceutical Company Limited announced the conclusion of its collaboration in the United States between Takeda Pharmaceuticals USA, Inc. f/k/a Takeda Pharmaceuticals North America, Inc. and Lilly to promote and market ACTOS, a partnership Takeda Pharmaceutical Company Limited described as "a great success" and "mutually beneficial to both companies."

ANSWER: Takeda and Eli Lilly admit that TPC issued a press release, on April 20, 2006, announcing the conclusion of the collaboration between TPUSA and Eli Lilly to promote ACTOS® in the United States, which contains the language quoted in paragraph 26. Takeda and Eli Lilly deny any remaining allegations of paragraph 26.

27. According to the American Diabetes Association, type II diabetes is the most common form of diabetes. Type II diabetes develops when the body does not produce enough insulin or doesn't efficiently use the insulin that it does produce. Type I diabetes occurs when the body does not produce any insulin at all. Insulin is necessary for the body to be able to use glucose for energy.

ANSWER: Takeda and Eli Lilly admit the allegations of paragraph 27.

28. ACTOS was approved by the Food and Drug Administration ("FDA") in July of 1999 to treat type II diabetes. ACTOS is in a class of insulin-sensitizing diabetes agents known as thiazolidinediones ("TZD"s).

ANSWER: Takeda and Eli Lilly admit that, on July 15, 1999, the FDA approved ACTOS® for prescription by licensed physicians in the United States as an adjunct to diet and exercise for the improvement of glycemic control in patients with type 2 diabetes as monotherapy or in combination with a sulfonylurea, metformin, or insulin. Takeda and Eli Lilly also admit that ACTOS® is a member of a class of medications known as thiazolidinediones. Takeda and Eli Lilly deny any remaining allegations of paragraph 28.

29. ACTOS exerts its antihyperglycemic effect only in the presence of endogenous insulin. Therefore, ACTOS is only used to treat type II diabetes and should not be used to treat type I diabetes.

ANSWER: Takeda and Eli Lilly admit that the FDA-approved labeling for ACTOS® states that ACTOS® exerts its antihyperglycemic effect only in the presence of endogenous insulin and that ACTOS® should not be used to treat type 1 diabetes. Takeda and Eli Lilly deny any remaining allegations of paragraph 29.

30. ACTOS is sold as a single ingredient product under the brand name ACTOS, and it is also sold in combination with metformin (Actoplus Met, Actoplus Met XR) and in combination with glimepiride (Duetact).

ANSWER: Takeda and Eli Lilly admit that, pursuant to approval by the FDA, pioglitazone HCl is marketed for prescription by licensed physicians in the United States as ACTOS®, in

combination with metformin as ACTOplus Met® and ACTOplus Met XR®, and in combination with glimepiride as Duetact®.

31. As a result of the defective nature of ACTOS, persons who were prescribed and ingested ACTOS for more than twelve (12) months, including Plaintiffs, have suffered and may continue to suffer from bladder cancer.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' prescriptions for and ingestion of ACTOS® and medical diagnoses. Takeda and Eli Lilly deny that ACTOS® causes bladder cancer and further deny the remaining allegations of paragraph 31.

32. Defendants concealed and continue to conceal their knowledge that ACTOS can cause bladder cancer from Plaintiffs/Decedents, other consumers, and the medical community. Specifically, Defendants have yet to adequately inform consumers and the prescribing medical community about the risks of bladder cancer with use of ACTOS for more than twelve (12) months.

ANSWER: Takeda and Eli Lilly deny that ACTOS® causes bladder cancer and further deny the remaining allegations of paragraph 32.

33. As a result of Defendants' actions and inactions, Plaintiffs/Decedents were injured due to their ingestion of ACTOS, which caused and will continue to cause Plaintiffs/Decedents various injuries and damages. Plaintiffs accordingly seek damages associated with these injuries.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' ingestion of ACTOS®. Takeda and Eli Lilly admit that Plaintiffs seek damages, but deny that Plaintiffs are entitled to damages of any kind. Takeda and Eli Lilly further deny the remaining allegations of paragraph 33.

34. Prior to ACTOS being approved by the FDA, a two-year carcinogenicity study was conducted on male and female rats. Drug-induced tumors were observed in male rats receiving doses of ACTOS that produced blood drug levels equivalent to those resulting from a clinical dose.

ANSWER: Takeda and Eli Lilly admit that tumors were observed in the urinary bladders of male rats who received 4mg/kg/day and above of pioglitazone HCl during a two-year carcinogenicity study conducted prior to FDA approval. Takeda and Eli Lilly further admit that results from the two-year carcinogenicity study in rats have been disclosed in the FDA-approved package insert since the FDA's approval of ACTOS® on July 15, 1999. Takeda and Eli Lilly deny the remaining allegations of paragraph 34.

35. In 2005, the results of the PROactive (PROspective PioglitAzone Clinical Trial In MacroVascular Events) three-year study were published. PROactive prospectively looked at the impact in total mortality and macrovascular morbidity using ACTOS. Dormandy J.A., et al. *Secondary Prevention of Macrovascular Events in Patients with Type 2 Diabetes in the PROactive Study (PROspective PioglitAzone Clinical Trial In MacroVascular Events): a Randomized Controlled Trial*, Lancet, 266:1279-1289 (2005).

ANSWER: Takeda and Eli Lilly admit that Dormandy J.A., *et al., Secondary Prevention of Macrovascular Events in Patients with Type 2 Diabetes in the PROactive Study (PROspective PioglitAzone Clinical Trial In MacroVascular Events): a Randomised Controlled Trial*, Lancet, 266:1279-1289 (2005) discusses results of the PROactive Study, a three-year clinical trial. Takeda and Eli Lilly also admit that a goal of the PROactive study was to ascertain whether pioglitazone reduces macrovascular morbidity and mortality in high-risk patients with type 2 diabetes. Takeda and Eli Lilly deny any remaining allegations of paragraph 35.

36. The PROactive study was looking at cardiovascular events and outcomes. However, the study demonstrated a higher percentage of bladder cancer cases in patients receiving ACTOS versus comparators. This information was not included in the published Dormandy paper.

ANSWER: Takeda and Eli Lilly admit that a goal of the PROactive study was to ascertain whether pioglitazone reduces macrovascular morbidity and mortality in high-risk patients with type 2 diabetes. Takeda and Eli Lilly further admit that, in the PROactive study, the researchers reported a higher percentage of bladder cancer cases in patients taking ACTOS® versus placebo,

but deny that this result was statistically significant. Takeda and Eli Lilly deny that ACTOS® causes bladder cancer and further deny the remaining allegations of paragraph 36.

37. A three-year liver safety study was also performed, and according to the FDA, that study also demonstrated a higher percentage of bladder cancer cases in patients receiving ACTOS versus comparators.

ANSWER: Takeda and Eli Lilly admit that the FDA has stated that a three-year liver safety study demonstrated a higher percentage of bladder cancer cases in patients receiving ACTOS® versus comparators. Takeda and Eli Lilly deny that ACTOS® causes bladder cancer and further deny any remaining allegations of paragraph 37.

38. On September 17, 2010, the FDA issued a Safety Announcement stating it was undertaking a review of the data from an ongoing, ten-year epidemiological study being conducted by Kaiser Permanente to evaluate the association between ACTOS and bladder cancer. The planned five-year interim analysis demonstrated that the risk of bladder cancer increases with increasing dose and duration of ACTOS use, reaching statistical significance after 24 months.

ANSWER: Takeda and Eli Lilly admit that, on September 17, 2010, the FDA issued a Safety Communication announcing that it was reviewing data from an ongoing ten-year epidemiological study by Takeda of patients with diabetes who are members of Kaiser Permanente Northern California designed to evaluate whether ACTOS® is associated with an increased risk of bladder cancer. Takeda and Eli Lilly further admit that, as reported in the FDA's September 17, 2010 Safety Communication, a planned five-year interim analysis of data from this study reported that there was no statistically significant association between ACTOS® exposure and the risk of bladder cancer, but that the risk of bladder cancer increased with increasing dose and duration of ACTOS® use, reaching statistical significance after 24 months of exposure. Takeda and Eli Lilly deny that ACTOS® causes bladder cancer and further deny the remaining allegations of paragraph 38.

39. Despite this finding by the FDA, Robert Spanheimer, Vice President of Medical and Scientific Affairs for Takeda, claimed to Reuters that the Kaiser Permanente study has not shown a risk to patients of bladder cancer or other cancers from ACTOS.

ANSWER: Takeda and Eli Lilly admit that Reuters has reported that Robert Spanheimer, Vice President of Medical and Scientific Affairs for TPUSA, stated in an interview that two ongoing trials being conducted by Kaiser Permanente have shown no risk to patients of bladder cancer or other cancers from ACTOS®. Takeda and Eli Lilly deny that ACTOS® causes bladder cancer and further deny any remaining allegations of paragraph 39.

40. In early 2011, the American Diabetes Association published *Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting*, Piccinni, et al. Diabetes Care, 34:1369-1371 (June 2011), published ahead of print April 22, 2011. This study looked at adverse events reports made to the FDA between 2004 and 2009. The conclusion of that study was that "[i]n agreement with preclinical and clinical studies, AERS analysis is consistent with an association between pioglitazone and bladder cancer. This issue needs constant epidemiologic surveillance and urgent definition by more specific studies."

ANSWER: Takeda and Eli Lilly admit that *Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting,* Piccinni, *et al*. Diabetes Care, 34:1369-1371 (June 2011) was published online on April 22, 2011, and that the publication includes the language quoted in paragraph 40. Takeda and Eli Lilly further admit that the study authors retrieved adverse event reports made to the FDA between 2004 and 2009 and that the study authors calculated a reporting odds ratio. Takeda and Eli Lilly deny that analysis of adverse event reports constitutes a reliable methodology for assessing causation, deny that ACTOS® causes bladder cancer, and further deny any remaining allegations of paragraph 40.

41. On June 9, 2011, the European Medicines Agency ("EMA") announced that it had been informed by the French Medicines Agency ("Afssaps") of its decision to suspend the use of pioglitazone-containing medicines (ACTOS, Competact) in France while awaiting the outcome of the ongoing European review.

ANSWER: Takeda and Eli Lilly admit that, on June 9, 2011, the European Medicines Agency ("EMA") announced that it had been informed by the French Medicines Agency ("Afssaps") of

its decision to suspend the use of pioglitazone-containing medicines (ACTOS®, Competact®) in France while awaiting the outcome of an ongoing European review. Takeda and Eli Lilly deny that ACTOS® causes bladder cancer and further deny any remaining allegations of paragraph 41.

42. France's decision was based upon a retrospective cohort study in France using the French National Health Insurance Plan which demonstrated a statistically significant increase in the risk for bladder cancer in males exposed to ACTOS for more than a year. The French cohort included 1.5 million patients with diabetes that were followed for 4 years (2006-2009).

ANSWER: Takeda and Eli Lilly admit that the French Medicines Agency's decision to suspend the use of pioglitazone-containing medicines reportedly was based on a retrospective cohort study in France conducted by Caisse National d'Assurance Maladie following patients in France taking antidiabetes medicines between 2006 and 2009. Takeda and Eli Lilly deny that ACTOS® causes bladder cancer and further deny any remaining allegations of paragraph 42.

43. On June 10, 2011, Reuters published that Germany had joined France in suspending the use of ACTOS after Germany's Federal Institute for Drugs and Medical Devices ("BfArM") reviewed the results of the French study. BfArM recommended that doctors should not put new patients on pioglitazone.

ANSWER: Takeda and Eli Lilly admit that Reuters reported, on June 10, 2011, that Germany had joined France in suspending the use of ACTOS® after receiving results of the study conducted by Caisse National d'Assurance Maladie, and that Germany's Federal Institute for Drugs and Medical Devices ("BfArM") recommended that doctors should not put new patients on pioglitazone. Takeda and Eli Lilly deny that ACTOS® causes bladder cancer and further deny any remaining allegations of paragraph 43.

44. On June 15, 2011, the FDA issued another Safety Announcement stating that "use of the diabetes medication ACTOS (pioglitazone) for more than one year may be associated with an increased risk of bladder cancer." The FDA ordered information about this risk to be added to the *Warnings and Precautions* section of the label for pioglitazone-containing medicines.

ANSWER: Takeda and Eli Lilly admit that, on June 15, 2011, the FDA issued a Safety Communication stating that use of ACTOS® for more than one year may be associated with an increased risk of bladder cancer. Takeda and Eli Lilly further admit that the FDA's June 15, 2011 Safety Communication stated that information about this risk will be added to the *Warnings and Precautions* section of the label for pioglitazone-containing medicines. Takeda and Eli Lilly deny that ACTOS® causes bladder cancer and further deny any remaining allegations of paragraph 44.

45. The FDA reported that the risk of bladder cancer increased with increasing dose and duration of pioglitazone use. When compared to persons never exposed to pioglitazone, exposed to pioglitazone therapy for longer than 12 months was associated with a 40% increase in risk. Based on this data, the FDA calculated that therapy with ACTOS for longer than 12 months was associated with 27.5 excess cases of bladder cancer per 100,000 person-years follow-up, compared to those who never used pioglitazone.

ANSWER: Takeda and Eli Lilly admit that the FDA's June 15, 2011 Safety Communication stated the results of Takeda's planned five-year interim analysis of patients with diabetes who are members of Kaiser Permanente Northern California showed that the risk of bladder cancer increased with increasing dose and duration of pioglitazone use, that when compared to never being exposed to pioglitazone, a duration of pioglitazone therapy longer than 12 months was associated with a 40% increase in risk, and that duration of therapy longer than 12 months was associated with 27.5 excess cases of bladder cancer per 100,000 person-years follow-up compared to those who never used pioglitazone. Takeda and Eli Lilly deny that ACTOS® causes bladder cancer and further deny any remaining allegations of paragraph 45.

46. On July 12, 2011, Takeda Pharmaceutical Company Limited issued a recall on ACTOS in France.

ANSWER: Takeda and Eli Lilly admit that, on July 11, 2011, TPC announced that its wholly-owned subsidiary, Laboratoires Takeda, was withdrawing pioglitazone-containing medicines

(ACTOS® and Competact®) in France at the request of Afssaps, the French Medicines Agency, following the decision by Afssaps to suspend the use of pioglitazone containing medicines for the treatment of type 2 diabetes. Takeda and Eli Lilly deny that ACTOS® causes bladder cancer and further deny any remaining allegations of paragraph 46.

47. As the manufacturers of ACTOS, Defendants knew or should have known that ACTOS use for longer than 12 months was associated with bladder cancer. Instead, Defendants promoted ACTOS as a safe and effective treatment for type II diabetes.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly deny that ACTOS® causes bladder cancer and further deny the remaining allegations of paragraph 47. Eli Lilly specifically denies any allegation that it is the manufacturer of ACTOS®.

48. Piccinni, et al. analyzed the association between antidiabetic drugs and bladder cancer by reviewing reports from the FDA Adverse Event Reporting System ("AERS") between 2004 and 2009. The association was analyzed by the case/noncase methodology. There were 31 recorded reports of bladder cancer in patients using pioglitazone. Piccinni's results indicated that the reporting odds ratio for pioglitazone was indicative of a "definite risk." *Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting*, Piccini, et al. Diabetes Care, 34:1369-1371 (June 2011), published ahead of print April 22, 2011.

ANSWER: Takeda and Eli Lilly admit that Piccinni, *et al*. reported the results of a study of adverse event reports made to the FDA between 2004 and 2009 in *Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting,* Diabetes Care, 34:1369-1371 (June 2011), which was published online on April 22, 2011. Takeda and Eli Lilly further admit that the study authors analyzed the association between pioglitazone use and bladder cancer through use of the case/noncase methodology, that the study authors calculated a reporting odds ratio, and that the study authors concluded that the reporting odds ratio was indicative of a "definite signal for bladder cancer associated with pioglitazone use." Further, Takeda and Eli Lilly admit that, based on the methodology that the study authors employed, 31

reports of bladder cancer concerned pioglitazone. Takeda and Eli Lilly deny that analysis of adverse event reports constitutes a reliable methodology for assessing causation, deny that ACTOS® causes bladder cancer, and further deny any remaining allegations of paragraph 48.

49. Despite its knowledge of this dangerous side effect that can result from ACTOS use, Defendants refused to warn patients, physicians and the medical community about the risk of bladder cancer.

ANSWER: Takeda and Eli Lilly deny that ACTOS® causes bladder cancer and further deny the remaining allegations of paragraph 49.

50. ACTOS is one of Defendants' top selling drugs. Upon information and belief, in the last year, the medication had global sales of $4.8 billion and accounted for approximately 27% of Takeda's revenue. In 2008, ACTOS was the tenth best-selling medication in the United States.

ANSWER: Takeda and Eli Lilly, on information and belief, admit that ACTOS® is one of Takeda's top-selling medications. Takeda and Eli Lilly further admit that Reuters reported, on June 10, 2011, that global sales of ACTOS® amounted to $4.8 billion, accounting for 27 percent of Takeda's revenue, and that the Wall Street Journal reported, on June 10, 2011, that ACTOS® was the tenth best-selling medication in the United States in 2008. Takeda and Eli Lilly deny any remaining allegations of paragraph 50.

51. Consumers, including Plaintiffs/Decedents, who have used ACTOS for treatment of type II diabetes, have several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits associated with long-term ACTOS therapy.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' use of ACTOS®. Takeda and Eli Lilly deny the remaining allegations of paragraph 51.

52. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiffs/Decedents and their physicians the true and significant risks associated with long-term ACTOS use.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 52.

53. As a result of Defendants' actions, Plaintiffs/Decedents and their prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiffs/Decedents had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 53.

54. Plaintiffs/Decedents were prescribed and began taking ACTOS upon direction of their physicians. Plaintiffs/Decedents subsequently developed bladder cancer.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' prescriptions for and use of ACTOS® and medical diagnoses. Takeda and Eli Lilly deny that ACTOS® causes bladder cancer and further deny the remaining allegations of paragraph 54.

55. As a direct result of being prescribed ACTOS for many years Plaintiffs/Decedents have been permanently and severely injured, having suffered serious consequences from long-term ACTOS use. Plaintiffs/Decedents require and will in the future require ongoing medical care and treatment.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' prescriptions for and use of ACTOS®. Takeda and Eli Lilly deny the remaining allegations of paragraph 55.

56. Plaintiffs/Decedents, as a direct and proximate result of long-term ACTOS use, suffered severe mental and physical pain and suffering and have and will sustain permanent injuries and emotional distress, along with economic loss due to medical expenses, and living related expenses due to their new lifestyle.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' use of ACTOS® and medical conditions. Takeda and Eli Lilly deny the remaining allegations of paragraph 56.

57. Plaintiffs/Decedents would not have used ACTOS had Defendants properly disclosed the risks associated with its long-term use.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' use of ACTOS®. Takeda and Eli Lilly deny the remaining allegations of paragraph 57.

FEDERAL REQUIREMENTS

58. Defendants had an obligation to comply with the law in the manufacture, design, and sale of ACTOS.

ANSWER: Takeda and Eli Lilly state that the allegations of paragraph 58 constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda and Eli Lilly, they admit that they complied with their duty under the law at all times. Takeda and Eli Lilly deny the remaining allegations of paragraph 58. Eli Lilly specifically denies any allegation that it is the manufacturer or designer of ACTOS®.

59. Upon information and belief, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq*.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 59.

60. With respect to the prescription drug ACTOS, the Defendants, upon information and belief, has or may have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

a. The prescription drug ACTOS is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements. See, 21 U.S.C. § 351.

b. The prescription drug ACTOS is adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from or its quality or purity falls below the standard set forth in the official compendium for ACTOS and such deviations are not plainly stated on their labels.

c. The prescription drug ACTOS is misbranded pursuant to 21 U.S.C. §352 because, among other things, its labeling is false or misleading.

d. The prescription drug ACTOS is misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e. The prescription drug ACTOS is misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

f. The prescription drug ACTOS is misbranded pursuant to 21 U.S.C. §352 because it's dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

g. The prescription drug ACTOS does not contain adequate directions for use pursuant to 21 CFR § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application.

h. The Defendants violated 21 CFR § 201.56 because the labeling was not informative and accurate.

i. The prescription drug ACTOS is misbranded pursuant to 21 CFR § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

j. The Defendants violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drug including the potential of ACTOS cause and the need for regular and/or consistent monitoring to ensure that a bladder cancer has not developed.

k. The Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug ACTOS.

l. The Defendants violated 21 CFR § 201.57 because the safety considerations regarding the prescription drug ACTOS are such that the drug should be reserved for certain situations, and the Defendants failed to state such information.

m. The prescription drug ACTOS is mislabeled pursuant to 21 CFR § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it, and steps that should be taken if they occur.

n. The prescription drug ACTOS is mislabeled pursuant to 21 CFR § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug.

o. The Defendants violated 21 CFR § 201.57 because the labeling failed to list the adverse reactions that occur with the prescription drug ACTOS and other drugs in the same pharmacologically active and chemically related class.

p. The Defendants violated 21 CFR § 201.57 because the possibility that a patient could develop bladder cancer; and yet the Defendants failed to list those developments before the other adverse reactions on the labeling of the prescription drug ACTOS.

q. The prescription drug ACTOS is mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established.

r. The prescription drug ACTOS violates 21 CFR § 210.1 because the process by which it was manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that they purport or are represented to possess.

s. The prescription drug ACTOS violates 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

t. The prescription drug ACTOS violates 21 CFR § 211.165 because the test methods employed by the Defendants are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

u. The prescription drug ACTOS violates 21 CFR § 211.165 in that the prescription drug ACTOS fails to meet established standards or specifications and any other relevant quality control criteria.

v. The prescription drug ACTOS violates 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drug ACTOS were not followed.

w. The prescription drug ACTOS violates 21 CFR § 310.303 in that the prescription drug ACTOS is not safe and effective for its intended use.

x. The Defendants violated 21 CFR § 310.303 because the Defendants failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

y. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with the prescription drug ACTOS as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse drugs experience.

z. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drug ACTOS, and evaluating the cause of the adverse event.

aa. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

bb. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

cc. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as "15-day Alert report," or "15-day Alert report follow-up."

dd. The Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of the prescription drug ACTOS or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

ee. The Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

ff. The Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15- day Alert reports based on information from the scientific literature.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 60, including all subparts. Eli Lilly specifically denies any allegation that it designed or manufactured ACTOS®, that it was the New Drug Application holder for ACTOS®, that it was contractually authorized pursuant to the co-promotion agreement with Takeda to communicate with the FDA regarding ACTOS® or change any labeling associated with the product, and that it had legal standing to seek modification of the FDA-approved labeling.

61. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiffs/Decedents, making the Defendants negligent *per se*.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 61.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

62. The running of any statute of limitation has been tolled by reason of Defendants' conduct. Defendants, through their affirmative misrepresentations and omissions, actively

concealed from Plaintiffs/Decedents and Plaintiffs/Decedents' prescribing physicians the true risks associated with Actos and pioglitazone hydrochloride.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 62.

63. As a result of Defendants' actions, Plaintiffs/Decedents and Plaintiffs/Decedents' prescribing physicians were unaware, and could not reasonably know or have learned through reasonable diligence that Plaintiffs/Decedents had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 63.

64. Furthermore, Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of Actos and pioglitazone hydrochloride. Defendants were under a duty to disclose the true character, quality and nature of Actos because this was non-public information which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to Plaintiffs/Decedents, their medical providers and/or to their health facilities.

ANSWER: Takeda and Eli Lilly state that the allegations of paragraph 64 constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda and Eli Lilly, they admit that they complied with their duty under the law at all times. Takeda and Eli Lilly deny the remaining allegations of paragraph 64.

65. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on Defendants' representations.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 65.

FIRST CAUSE OF ACTION
AGAINST THE DEFENDANTS
NEGLIGENCE

66. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: Takeda and Eli Lilly incorporate by reference the preceding paragraphs of this Answer as if fully set forth herein.

67. Defendants had a duty to exercise the care of an expert in all aspects of the formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, and sale of ACTOS to ensure the safety of ACTOS and to ensure that the consuming public, including the Plaintiffs/Decedents and Plaintiffs/Decedents' physicians and agents, obtained accurate information and instructions for the use of ACTOS.

ANSWER: Takeda and Eli Lilly state that the allegations of paragraph 67 constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda and Eli Lilly, they admit that they complied with their duty under the law at all times. Takeda and Eli Lilly deny the remaining allegations of paragraph 67. Eli Lilly specifically denies any allegation that it is the manufacturer of ACTOS®.

68. Defendants owed a duty toward foreseeable users of ACTOS drug products to exercise reasonable care to ensure that ACTOS drugs were reasonably safe for ordinary and intended uses, and specifically, *inter alia*, to ensure through adequate testing, labeling, and otherwise, that physicians who would be likely to prescribe the products for their patients' use were adequately informed as to the potential effects of using the products in ordinary and foreseeable ways, in particular the risks increased bladder cancer, heart attacks, and cardiac arrhythmias.

ANSWER: Takeda and Eli Lilly state that the allegations of paragraph 68 constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda and Eli Lilly, they admit that they complied with their duty under the law at all times. Takeda and Eli Lilly deny that ACTOS® causes bladder cancer and further deny the remaining allegations of paragraph 68.

69. Defendants failed to exercise reasonable care in testing ACTOS for side effects in ordinary and foreseeable users; and failed to disseminate to physicians accurate and truthful information concerning the effects of ACTOS; thus, physicians were not able to make informed choices concerning the use of ACTOS drug products.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 69.

70. Defendants failed to exercise ordinary care in the manufacture, sale, testing, marketing, quality, assurance, quality control and/or distribution of ACTOS into the stream of commerce in that Defendants knew or should have known that ACTOS drug products created a foreseeable high risk of unreasonable, dangerous side effects and health hazards.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 70. Eli Lilly specifically denies any allegation that it manufactured ACTOS®.

71. The dangerous propensities of ACTOS drug products as referenced above, were known or scientifically knowable, through appropriate research and testing, to the Defendants at the time it distributed, supplied, or sold the products, and not known to ordinary physicians who would be expected to prescribe ACTOS for the Plaintiffs/Decedents and other patients, similarly situated.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly deny the remaining allegations of paragraph 71.

72. The information Defendants disseminated to physicians concerning ACTOS drug products was, in fact, inaccurate, misleading, and otherwise inadequate, as described above.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 72.

73. As a proximate result, the Plaintiffs/Decedents suffered grievous bodily injuries and consequent economic and other losses when they ingested ACTOS.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' ingestion of ACTOS®. Takeda and Eli Lilly deny the remaining allegations of paragraph 73.

74. The Defendants were negligent, and breached their duties of reasonable care to the Plaintiffs/Decedents with respect to ACTOS drug products in one or more of the following respects:

(a) Despite knowledge of hazards and knowledge that the product was frequently prescribed for the use, Defendants failed to accompany the product with adequate warnings and instructions regarding the adverse and long lasting side effects associated with the use of ACTOS;

(b) Defendants failed to conduct adequate testing;

(c) Despite knowledge of hazards, Defendants failed to conduct adequate post-marketing surveillance to determine the safety of the product;

(d) Despite knowledge of hazards, Defendants failed to adequately warn Plaintiffs/Decedents' physicians or the Plaintiffs/Decedents that the use of ACTOS drug products could result in severe side effects as described above;

(e) Despite the fact that the Defendants knew or should have known that their ACTOS drug products caused unreasonably dangerous side effects, Defendants failed to adequately disclose the known or knowable risks associated with ACTOS as set forth above; Defendants willfully and deliberately failed to adequately disclose these risks, and in doing so, acted with a conscious disregard of the Plaintiffs/Decedents safety and/or welfare;

(f) Defendants failed to design, develop, implement, administer, supervise and monitor its clinical trials for ACTOS; and

(g) Defendants, in its promotion of ACTOS, were overly aggressive and deceitful, and promoted ACTOS in a fraudulent manner, despite evidence known to Defendants that ACTOS was dangerous.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 74, including all subparts.

Eli Lilly specifically denies any allegation that it designed or manufactured ACTOS®.

75. As a direct and proximate result of the wrongful acts of the Defendants, the Plaintiffs/Decedents developed severe side effects as described herein, and suffered irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiffs/Decedents' earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiffs/Decedents' injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 75.

76. The negligence, carelessness, and the willful and wanton misconduct of the Defendants was a proximate cause of Plaintiffs/Decedents' harms and injuries that the Decedents suffered and Plaintiffs will continue to suffer.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 76.

77. In the alternative, Defendants' acts of omissions and concealment of material facts of the design and manufacturing defects were made with the understanding that patients and physicians would rely upon such statements when choosing ACTOS drug products.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 77.

78. Furthermore, the economic damages and physical harm caused by Defendants' conduct would not have occurred had Defendants exercised the high degree of care imposed upon it.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 78.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs/Decedents for their injuries and which will deter the Defendants and others from like conduct.

ANSWER: Takeda and Eli Lilly admit that Plaintiffs seek judgment and damages, but deny that Plaintiffs are entitled to judgment, damages, or relief of any kind. Takeda and Eli Lilly further deny the remaining allegations of this unnumbered paragraph.

SECOND CAUSE OF ACTION
AGAINST THE DEFENDANTS
STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN

79. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: Takeda and Eli Lilly incorporate by reference the preceding paragraphs of this Answer as if fully set forth herein.

80. At all relevant times the Defendants were engaged in the business of manufacturing, designing, testing, marketing, promoting, distributing, and/or selling ACTOS.

ANSWER: Takeda admits that, pursuant to approval by the FDA, TPC has manufactured ACTOS®, TPA has sold, marketed and distributed ACTOS®, Eli Lilly marketed ACTOS® from 1999 to 2006, and TPUSA has marketed ACTOS® for prescription by licensed physicians in the United States. Takeda denies the remaining allegations of paragraph 80.

Eli Lilly admits that, pursuant to approval by the FDA, it marketed ACTOS® from 1999 to 2006 for prescription by licensed physicians in the United States. Eli Lilly also admits, on information and belief, that, pursuant to approval by the FDA, TPC manufactures ACTOS®, TPUSA markets ACTOS®, and TPA sells, markets, and distributes ACTOS® for prescription by licensed physicians in the United States. Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 80. Eli Lilly specifically denies any allegation that it manufactured or designed ACTOS®.

81. ACTOS is defective and unreasonably dangerous to consumers.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 81.

82. At all times mentioned in this Complaint ACTOS was defective and/or unreasonably dangerous to Plaintiffs/Decedents and other foreseeable users at the time it left the control of the Defendants.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 82.

83. ACTOS is defective in its design or formulation in that when it left the hands of the Defendants, its foreseeable risks exceed the benefits associated with its design and formulation and/or it was more dangerous than an ordinary consumer would expect.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly deny the remaining allegations of paragraph 83.

84. The foreseeable risks associated with the design or formulation of ACTOS, include, but are not limited to, the fact that the design or formulation of ACTOS is more dangerous than a reasonably prudent consumer would expect when used in an intended and reasonably foreseeable manner.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly deny the remaining allegations of paragraph 84.

85. At all times material to this action, ACTOS was expected to reach, and did reach consumers in the States of Florida, South Dakota and Washington and throughout the United States, including the Plaintiffs/Decedents, without substantial change in the condition in which it was sold.

ANSWER: Takeda and Eli Lilly admit that ACTOS® was expected to reach intended consumers without substantial change in the condition in which it was sold. Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the allegation of paragraph 85 that ACTOS® "did reach" intended consumers, including Plaintiffs, without substantial change in the condition in which it was sold. Takeda and Eli Lilly deny the remaining allegations of paragraph 85.

86. Defendants, developed, marketed and distributed ACTOS drug products to the general public even after learning of the design and manufacturing defects that threatened the intended use of ACTOS.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 86.

87. Defendants knew or should have known through testing, adverse event reporting, or otherwise, that ACTOS created a high risk of bodily injury and serious harm.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 87.

88. The dangerous propensities of ACTOS drug products were known or scientifically knowable, through appropriate research and testing, to the Defendants at the time said Defendants distributed, supplied, or sold ACTOS, and not known to ordinary physicians who would be expected to prescribe ACTOS for their patients.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly deny the remaining allegations of paragraph 88.

89. ACTOS drug products, as distributed, were defective and unreasonably dangerous inasmuch as ACTOS were not accompanied by warnings and instructions that were appropriate and adequate to render ACTOS reasonably safe for their ordinary, intended, and reasonably foreseeable uses, in particular the common, foreseeable, and intended use of ACTOS.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 89.

90. In order to advance Defendant's own pecuniary interests, Defendants intentionally proceeded with the manufacturing, the sale and distribution, and marketing of ACTOS drug products with knowledge that consumers would be exposed to serious danger.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 90. Eli Lilly specifically denies any allegation that it manufactured ACTOS®.

91. At all times material to this action, ACTOS was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a "defective" and "unreasonably dangerous" condition, at the time it was placed in the stream of commerce in ways that include, but are not limited to one or more of the particulars:

a. At the time ACTOS left the control of the Defendants ACTOS was defective and unreasonably dangerous due to a failure to contain adequate warnings or instructions, or, in the alternative, because it was designed in a defective manner, or, in the alternative, because ACTOS breached an express warranty or failed to conform to other expressed factual representations upon which Plaintiffs/Decedents' physicians justifiably relied, or because it breached an implied warranty, all of which proximately caused the damages for which Plaintiffs/Decedents seek recovery herein;

b. ACTOS drug products were not reasonably safe as designed, taking into account the foreseeable risks involved in its use at the time ACTOS left the possession of the Defendants, and that such risks clearly outweighed the utility of ACTOS therapy or its therapeutic benefits, and subjected Plaintiffs/Decedents to the risk of suffering avoidable bladder cancer, heart attacks, and cardiac arrhythmias;

c. At the time ACTOS left the control of the Defendants ACTOS possessed a dangerous characteristic that may cause damage and it was not reasonably safe due to inadequate or defective warnings or instructions that were known or reasonably scientifically knowable at the time ACTOS left the possession of the Defendants. Specifically, although the Defendants were well aware that ACTOS products could potentially cause severe side effects;

d. The Defendants' warnings or instructions were not of a nature that a reasonably prudent drug company in the same or similar circumstances would have provided with respect to the danger. There were no warnings or instructions that communicate sufficient information on the dangers and safe use of ACTOS taking into account the characteristics of the ACTOS, and/or the ordinary knowledge common to the physician who prescribes and the consumer who purchases ACTOS, such as the Plaintiffs/Decedents;

e. ACTOS manufactured and supplied by the Defendants were further defective due to inadequate post-marketing warning or instruction because, after the Defendants knew or should have known of the risks of injury from ACTOS drug products associated with the use as commonly prescribed, Defendants failed to promptly respond to and adequately warn about the risks of suffering avoidable bladder cancer, heart attacks, and cardiac arrhythmias associated with the use of ACTOS;

f. When placed in the stream of commerce, ACTOS was defective in design and formulation, making the use of ACTOS more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with other similar drugs on the market; and

g. ACTOS was insufficiently tested.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly deny the remaining allegations of paragraph 91, including all subparts. Eli Lilly specifically denies any allegation that it designed or manufactured ACTOS®.

92. The Defendants knew, or in light of reasonably available scientific knowledge should have known, about the danger that caused the injuries for which the Plaintiffs/Decedents seek recovery.

ANSWER: Takeda and Eli Lilly admit that Plaintiffs seek damages and other relief, but deny that Plaintiffs are entitled to damages or relief of any kind. Takeda and Eli Lilly further deny the remaining allegations of paragraph 92.

93. The Defendants knew or in light of reasonably available scientific knowledge should have known about the danger associated with use of ACTOS that caused the damages for which Plaintiffs/Decedents seek recovery.

ANSWER: Takeda and Eli Lilly admit that Plaintiffs seek damages and other relief, but deny that Plaintiffs are entitled to damages or relief of any kind. Takeda and Eli Lilly further deny the remaining allegations of paragraph 93.

94. The reasonably foreseeable use of ACTOS involved substantial dangers not readily recognizable by the ordinary physician who prescribed ACTOS or the patient, including the Plaintiffs/Decedents, who consumed ACTOS drug products.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' use of ACTOS®. Takeda and Eli Lilly deny the remaining allegations of paragraph 94.

95. The Defendants knew that ACTOS drug products were to be prescribed by physicians and used by consumers without inspection for defects in the product or in any of its components or ingredients and that ACTOS was not properly prepared nor accompanied by adequate warnings of the dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly deny the remaining allegations of paragraph 95.

96. Plaintiffs/Decedents and Plaintiffs/Decedents' physicians did not know, nor had reason to know, at the time of the use of Defendants' ACTOS drug products, or at any time prior to its use, of the existence of the above-described defects and inadequate warnings.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' use of ACTOS®. Takeda and Eli Lilly deny the remaining allegations of paragraph 96.

97. The above defects caused serious injuries to Plaintiffs/Decedents when ACTOS was used in its intended and foreseeable manner, and in the manner recommended by the Defendants and/or in a non-intended manner that was reasonably foreseeable.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' use of ACTOS®. Takeda and Eli Lilly deny the remaining allegations of paragraph 97.

98. In addition, at the time that ACTOS left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced

the risk of Plaintiffs/Decedents' injuries without impairing the reasonably anticipated or intended function of ACTOS. These safer designs were economically and technologically feasible and would have prevented or significantly reduced the risk of Plaintiffs/Decedents' injuries without substantially impairing ACTOS' utility.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 98.

99. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiffs/Decedents suffered severe and irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiffs/Decedents' earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiffs/Decedents' injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 99.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs/Decedents for their injuries and which will deter the Defendants and others from like conduct.

ANSWER: Takeda and Eli Lilly admit that Plaintiffs seek judgment and damages, but deny that Plaintiffs are entitled to judgment, damages, or relief of any kind. Takeda and Eli Lilly further deny the remaining allegations of this unnumbered paragraph.

THIRD CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
STRICT PRODUCTS LIABILITY - MANUFACTURING DEFECT

100. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: Takeda and Eli Lilly incorporate by reference the preceding paragraphs of this Answer as if fully set forth herein.

101. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling ACTOS.

ANSWER: Takeda admits that, pursuant to approval by the FDA, TPC has researched and manufactured ACTOS®, TPA has sold, marketed and distributed ACTOS®, Eli Lilly marketed

ACTOS® from 1999 to 2006, and TPUSA has marketed ACTOS® for prescription by licensed physicians in the United States. Takeda denies the remaining allegations of paragraph 101.

Eli Lilly admits that, pursuant to approval by the FDA, it marketed ACTOS® from 1999 to 2006 for prescription by licensed physicians in the United States. Eli Lilly also admits, on information and belief, that, pursuant to approval by the FDA, TPC manufactures ACTOS®, TPUSA markets ACTOS®, and TPA sells, markets, and distributes ACTOS®, for prescription by licensed physicians in the United States. Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 101. Eli Lilly specifically denies any allegation that it manufactured or designed ACTOS®.

102. At all times material to this action, ACTOS was expected to reach, and did reach consumers in the States of Florida, South Dakota and Washington and throughout the United States, including the Plaintiffs/Decedents, without substantial change in the condition from which it was sold.

ANSWER: Takeda and Eli Lilly admit that ACTOS® was expected to reach intended consumers without substantial change in the condition in which it was sold. Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegation of paragraph 102 that ACTOS® "did reach" intended consumers, including Plaintiffs, without substantial change in the condition in which it was sold. Takeda and Eli Lilly deny the remaining allegations of paragraph 102.

103. At all times material to this action, ACTOS was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways that include, but are not limited to, one or more of the following particulars posing a serious risk of injury and death.

a. When placed in the stream of commerce, ACTOS contained manufacturing defects that rendered the product unreasonably dangerous;

b. ACTOS manufacturing defects occurred while the product was in the possession and control of the Defendants;

c. ACTOS was not made in accordance with the Defendants' product specifications or performance standards; and

d. ACTOS's manufacturing defects existed before it left the control of the Defendants.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 103, including all subparts. Eli Lilly specifically denies any allegation that it designed or manufactured ACTOS®.

104. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiffs/Decedents suffered severe and irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiffs/Decedents' earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiffs/Decedents' injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 104.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs/Decedents for their injuries and which will deter the Defendants and others from like conduct.

ANSWER: Takeda and Eli Lilly admit that Plaintiffs seek judgment and damages, but deny that Plaintiffs are entitled to judgment, damages, or relief of any kind. Takeda and Eli Lilly further deny the remaining allegations of this unnumbered paragraph.

FOURTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
STRICT PRODUCTS LIABILITY - FAILURE TO WARN

105. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: Takeda and Eli Lilly incorporate by reference the preceding paragraphs of this Answer as if fully set forth herein.

106. ACTOS was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including the Plaintiffs/Decedents and/or their health care providers, of the dangerous risks and reactions

associated with ACTOS, including but not limited to its propensity to cause avoidable bladder cancer, heart attacks, and cardiac arrhythmias, and other serious injuries and side effects despite the Defendants' knowledge of the increased risk of these injuries over similar drugs.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 106.

107. ACTOS was defective due to inadequate post-marketing warnings or instruction because after Defendants knew or should have known of the risk and danger of serious bodily harm and/or death from the use of ACTOS, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and/or death.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 107.

108. Plaintiffs/Decedents were prescribed and used ACTOS for its intended purpose.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 108.

109. Plaintiffs/Decedents could not have known about the dangers and hazards presented by ACTOS.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly deny the remaining allegations of paragraph 109.

110. The warnings that were given by the Defendants were not accurate, clear, complete and/or were ambiguous.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 110.

111. The warnings that were given by the Defendants failed to properly warn physicians of the increased risks of bladder cancer, heart attacks, cardiac arrhythmias and other serious injuries and side effects, and failed to instruct physicians to test and monitor for the presence of the injuries for which Plaintiffs/Decedents and others had been placed at risk.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 111.

112. The warnings that were given by the Defendants failed to properly warn consumers of the increased risk of bladder cancer, heart attacks, cardiac arrhythmias, and other serious injuries and side effects.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 112.

113. Plaintiffs/Decedents, individually and through their prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of the Defendants. The Defendants had a continuing duty to warn the Plaintiffs/Decedents of the dangers associated with ACTOS. Had the Plaintiffs/Decedents received adequate warnings regarding the risks of ACTOS, they would not have used ACTOS.

ANSWER: Takeda and Eli Lilly state that the allegations of paragraph 113 regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda or Eli Lilly, they admit that they complied with their duty under the law at all times. Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' use of ACTOS®. Takeda and Eli Lilly deny the remaining allegations of paragraph 113.

114. As a direct and proximate result of ACTOS's defective and inappropriate warnings, the Plaintiffs/Decedents suffered severe physical injuries and damages as described above.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 114.

115. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiffs/Decedents suffered severe and irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiffs/Decedents' earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiffs/Decedents' injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 115.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs/Decedents for their injuries and which will deter the Defendants and others from like conduct.

ANSWER: Takeda and Eli Lilly admit that Plaintiffs seek judgment and damages, but deny that Plaintiffs are entitled to judgment, damages, or relief of any kind. Takeda and Eli Lilly further deny the remaining allegations of this unnumbered paragraph.

FIFTH CAUSE OF ACTION
AGAINST THE DEFENDANTS
BREACH OF EXPRESS WARRANTY

116. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: Takeda and Eli Lilly incorporate by reference the preceding paragraphs of this Answer as if fully set forth herein.

117. Defendants' expressly warranted to the Plaintiffs/Decedents that ACTOS drug products were safe and effective.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly deny the remaining allegations of paragraph 117.

118. In response to these promises and express statements, Plaintiffs/Decedents and Plaintiffs/Decedents' physicians relied on such affirmations and warranties.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 118.

119. ACTOS drug products do not conform to those express representations in light of recently discovered disclosures and information previously withheld by Defendants. Defendants' express warranty through its false statements failed to disclose design, manufacturing and safety defects inherent in ACTOS.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 119.

120. Defendants breached its warranties of ACTOS by continuing sales and marketing campaigns highlighting the safety of its ACTOS drug products, while it knew of the design, manufacturing and safety defects and the risk of bladder cancer, heart attacks, and cardiac arrhythmias, as described throughout this Complaint.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 120.

121. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiffs/Decedents developed severe side effects as described herein, and suffered irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiffs/Decedents' earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiffs/Decedents' injuries; suffered and will continue

to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 121.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs/Decedents for their injuries and which will deter the Defendants and others from like conduct.

ANSWER: Takeda and Eli Lilly admit that Plaintiffs seek judgment and damages, but deny that Plaintiffs are entitled to judgment, damages, or relief of any kind. Takeda and Eli Lilly further deny the remaining allegations of this unnumbered paragraph.

SIXTH CAUSE OF ACTION
AGAINST THE DEFENDANTS
BREACH OF IMPLIED WARRANTIES

122. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: Takeda and Eli Lilly incorporate by reference the preceding paragraphs of this Answer as if fully set forth herein.

123. The Defendants knew that most physicians who prescribed ACTOS drug products were not aware of the serious side effects as described herein associated with use of ACTOS. The Defendants also knew that the risks of said side effects were much greater than most physicians realized. By failing to give adequate warnings about these side effects and the risk of the use that is associated with those side effects, the Defendants breached implied warranties of merchantability and fitness for the ordinary use of ACTOS.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly deny the remaining allegations of paragraph 123.

124. At all times mentioned in this Complaint, the Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied and sold ACTOS drug products and prior to the time ACTOS was used by Plaintiffs/Decedents, the Defendants impliedly warranted to Plaintiffs/Decedents and to Plaintiffs/Decedents' physicians that ACTOS were of merchantable quality and safe and fit for the use for which ACTOS were intended.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' use of ACTOS®. Takeda and Eli Lilly, on information and belief, further admit that, pursuant to approval by the FDA, TPC has manufactured ACTOS®, TPA has sold, marketed and distributed ACTOS®, and TPUSA has marketed ACTOS® for prescription by licensed physicians in the United States. Takeda and Eli Lilly also admit that, pursuant to approval by the FDA, Eli Lilly marketed ACTOS® from 1999 to 2006 for prescription by licensed physicians in the United States. Takeda and Eli Lilly deny the remaining allegations of paragraph 124. Eli Lilly specifically denies any allegation that it designed or manufactured ACTOS®.

125. Plaintiffs/Decedents relied on the skill and judgment of the Defendants in using ACTOS drug products.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 125.

126. ACTOS drug products were not safe and were unfit for their intended use, nor were ACTOS of merchantable quality, as warranted by the Defendants, in that ACTOS had very dangerous propensities when put to intended use and would cause severe injury to the user. ACTOS drug products were not properly prepared nor accompanied by adequate warnings of ACTOS dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution. As a result, ACTOS drug products proximately caused Plaintiffs/Decedents to sustain damages and injuries as alleged in this Complaint.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 126.

127. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiffs/Decedents developed severe side effects as described herein, and suffered irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiffs/Decedents' earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiffs/Decedents' injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 127.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs/Decedents for their injuries and which will deter the Defendants and others from like conduct.

ANSWER: Takeda and Eli Lilly admit that Plaintiffs seek judgment and damages, but deny that Plaintiffs are entitled to judgment, damages, or relief of any kind. Takeda and Eli Lilly further deny the remaining allegations of this unnumbered paragraph.

SEVENTH CAUSE OF ACTION
AGAINST THE DEFENDANTS
BREACH OF IMPLIED WARRANTY FOR A PARTICULAR PURPOSE

128. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: Takeda and Eli Lilly incorporate by reference the preceding paragraphs of this Answer as if fully set forth herein.

129. At all times herein mentioned, Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Actos and pioglitazone hydrochloride, to treat Type 2 Diabetes Mellitus.

ANSWER: Takeda admits that, pursuant to approval by the FDA, TPC has manufactured ACTOS®, TPA has sold, marketed and distributed ACTOS®, Eli Lilly marketed ACTOS® from 1999 to 2006, and TPUSA has marketed ACTOS® for prescription by licensed physicians in the United States as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Takeda denies the remaining allegations of paragraph 129.

Eli Lilly admits that, pursuant to approval by the FDA, it marketed ACTOS® from 1999 to 2006 for prescription by licensed physicians in the United States as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Eli Lilly also admits, on information and belief, that, pursuant to approval by the FDA, TPC manufactures ACTOS®, TPUSA markets ACTOS®, and TPA sells, markets, and distributes ACTOS®, for prescription by licensed physicians in the United States as an adjunct to diet and exercise to

improve glycemic control in adults with type 2 diabetes mellitus. Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 129. Eli Lilly specifically denies any allegation that it manufactured or designed ACTOS®.

130. Defendants impliedly represented and warranted to the users of Actos that Actos was safe and fit for the particular purpose for which said product was to be used, namely treating diabetes, improving health, maintaining health, and potentially prolonging life.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly deny the remaining allegations of paragraph 130.

131. These representations and warranties aforementioned were false, misleading, and inaccurate in that Actos and pioglitazone hydrochloride were unsafe, degraded Plaintiffs/Decedents' health and shortened their life expectancy.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 131.

132. Plaintiffs/Decedents relied on the implied warranty of fitness for a particular use and purpose.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 132.

133. Plaintiffs/Decedents reasonably relied upon the skill and judgment of Defendants as to whether Actos was safe and fit for its intended use.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly deny the remaining allegations of paragraph 133.

134. Actos and pioglitazone hydrochloride were injected into the stream of commerce by Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

ANSWER: Takeda and Eli Lilly admit that ACTOS® was expected to reach intended consumers without substantial change in the condition in which it was sold. Takeda and Eli Lilly deny the remaining allegations of paragraph 134.

135. Defendants breached the aforesaid implied warranty, as their drug Actos was not fit for its intended purposes and uses.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 135.

136. As a direct and proximate result of the forgeoing, Plaintiffs/Decedents developed severe side effects as described herein, and suffered irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiffs/Decedents' earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiffs/Decedents' injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 136.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs/Decedents for their injuries and which will deter the Defendants and others from like conduct.

ANSWER: Takeda and Eli Lilly admit that Plaintiffs seek judgment and damages, but deny that Plaintiffs are entitled to judgment, damages, or relief of any kind. Takeda and Eli Lilly further deny the remaining allegations of this unnumbered paragraph.

EIGHTH CAUSE OF ACTION
AGAINST THE DEFENDANTS
FRAUDULENT MISREPRESENTATION

137. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: Takeda and Eli Lilly incorporate by reference the preceding paragraphs of this Answer as if fully set forth herein.

138. Defendants had actual knowledge of facts, which demonstrated that representations in the package insert, and/or the PDR monograph, and/or literature, and/or other mediums that the Defendants distributed concerning their ACTOS drug products were false and misleading. Defendants had an absolute duty to disclose the true facts regarding the safety of ACTOS to physicians and their patients and the medical community, which they negligently failed to do. Furthermore, Defendants had a duty to ensure that they had a reasonable basis for making the representations described above, to exercise reasonable care in making those representations, to accurately make those representations, and to not make misrepresentations concerning ACTOS, all of which Defendants failed to do.

ANSWER: Takeda and Eli Lilly state that the allegations of paragraph 138 regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda or Eli Lilly, they admit that they complied with their duty under the law at all times. Takeda and Eli Lilly deny the remaining allegations of paragraph 138.

139. Important information regarding the risk of ACTOS was in the exclusive control of Defendants and was exclusively known by Defendants. In the furtherance of Defendants' own interests, Defendants disseminated false information regarding ACTOS to physician and Plaintiffs/Decedents and did so knowing that the safety of ACTOS depended on the accuracy of that information. Further, Defendants knew and expected that recipients of that information would rely on the information that the recipients would take action based upon the information, and that individuals would be put in peril by such actions and that those individuals would suffer physical harm as a result.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 139.

140. Defendants expressly and/or impliedly represented to Plaintiffs/Decedents, Plaintiffs/Decedents ' physicians, the medical community, and members of the general public that their ACTOS drugs were safe for use. The representations by Defendants were, in fact, false. The true facts were that ACTOS was not safe for its intended use and was, in fact, dangerous to the health and body of the Plaintiffs/Decedents.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly deny the remaining allegations of paragraph 140.

141. Defendants made the above-described representations with no reasonable grounds for believing them to be true. Defendants did not have accurate or sufficient information concerning these representations and they failed to exercise reasonable care both in ascertaining the accuracy of the information contained in those representations and in communicating the information.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 141.

142. The aforementioned misrepresentations or omissions were made to the Plaintiffs/Decedents, and Plaintiffs/Decedents' physicians, and the medical community, all of whom justifiably and foreseeably relied on those representations or omissions. Plaintiffs/Decedents would not have suffered injuries but for the above misrepresentations or

omissions of Defendants. Thus, Defendants and Defendants' misrepresentations or omissions were a cause in fact and a proximate cause of Plaintiffs/Decedents' damages.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 142.

143. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiffs/Decedents developed severe side effects as described herein, and suffered irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiffs/Decedents' earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiffs/Decedents' injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 143.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs/Decedents for their injuries and which will deter the Defendants and others from like conduct.

ANSWER: Takeda and Eli Lilly admit that Plaintiffs seek judgment and damages, but deny that Plaintiffs are entitled to judgment, damages, or relief of any kind. Takeda and Eli Lilly further deny the remaining allegations of this unnumbered paragraph.

NINTH CAUSE OF ACTION
AGAINST THE DEFENDANTS
FRAUDULENT CONCEALMENT

144. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: Takeda and Eli Lilly incorporate by reference the preceding paragraphs of this Answer as if fully set forth herein.

145. At all times during the course of dealing between Defendants and Plaintiffs/Decedents, and/or Plaintiffs/Decedents' healthcare providers, and/or the FDA, Defendants misrepresented the safety of ACTOS for its intended use.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 145.

146. Defendants knew or were reckless in not knowing that its representations were false.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 146.

147. In representations to Plaintiffs/Decedents, and/or Plaintiffs/Decedents' healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

a. that ACTOS was not safe;

b. that the risks of adverse events with ACTOS were high;

c. that the risks of adverse events with ACTOS were not adequately tested and/or known by Defendants;

d. that Defendants were aware of dangers in ACTOS, in addition to and above and beyond those associated with alternative medications;

e. that ACTOS was defective, and that it caused dangerous side effects;

f. that patients needed to be monitored more regularly than normal while using ACTOS;

g. that ACTOS was manufactured negligently;

h. that ACTOS was manufactured defectively;

i. that ACTOS was manufactured improperly;

j. that ACTOS was designed negligently;

k. that ACTOS was designed defectively; and

l. that ACTOS was designed improperly.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 147, including all subparts. Eli Lilly specifically denies any allegation that it manufactured or designed ACTOS®.

148. Defendants were under a duty to disclose to Plaintiffs/Decedents, and their physicians, hospitals, healthcare providers, and/or the FDA the defective nature of ACTOS, including but not limited to bladder cancer, heart attacks, and cardiac arrhythmias.

ANSWER: Takeda and Eli Lilly state that the allegations of paragraph 148 constitute legal conclusions to which no response is required. To the extent that these allegations are construed

as factual allegations directed to Takeda and Eli Lilly, they admit that they complied with their duty under the law at all times. Takeda and Eli Lilly deny the remaining allegations of paragraph 148.

149. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used ACTOS, including the Plaintiffs/Decedents, in particular.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 149.

150. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of ACTOS was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiffs/Decedents, and their physicians, hospitals and healthcare providers into reliance, continued use of ACTOS, and actions thereon, and to cause them to purchase, prescribe, and/or dispense ACTOS and/or use the product.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 150.

151. Defendants knew that Plaintiffs/Decedents, and their physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding ACTOS, as set forth herein.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 151.

152. Plaintiffs/Decedents, as well as their doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 152.

153. As a result of the foregoing acts and omissions the Plaintiffs/Decedents were and still are caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, bladder cancer, heart attacks, and cardiac arrhythmias, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 153.

154. As a result of the foregoing acts and omissions the Plaintiffs/Decedents require and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs/Decedents are informed and believe and further allege that Plaintiffs/Decedents will in the future be required to obtain further medical and/or hospital care, attention, and services.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 154.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs/Decedents for their injuries and which will deter the Defendants and others from like conduct.

ANSWER: Takeda and Eli Lilly admit that Plaintiffs seek judgment and damages, but deny that Plaintiffs are entitled to judgment, damages, or relief of any kind. Takeda and Eli Lilly further deny the remaining allegations of this unnumbered paragraph.

TENTH CAUSE OF ACTION
AGAINST THE DEFENDANTS
NEGLIGENT MISREPRESENTATION

155. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: Takeda and Eli Lilly incorporate by reference the preceding paragraphs of this Answer as if fully set forth herein.

156. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiffs/Decedents, the FDA and the public in general that said product, ACTOS, had been tested and found to be a safe and effective form of therapy.

ANSWER: Takeda and Eli Lilly state that the allegations of paragraph 156 constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda and Eli Lilly, they admit that they complied with their duty under the law at all times. Takeda and Eli Lilly deny the remaining allegations of paragraph 156.

157. The representations made by Defendants were, in fact, false.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 157.

158. Defendants failed to exercise ordinary care in the representation of ACTOS, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of

said product into interstate commerce in that Defendants negligently misrepresented ACTOS's high risk of unreasonable, dangerous side effects.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 158. Eli Lilly specifically denies any allegation that it is the manufacturer of ACTOS®.

159. Defendants breached their duty in representing ACTOS's serious side effects to the medical and healthcare community, to the Plaintiffs/Decedents, the FDA and the public in general.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 159.

160. As a result of the negligent misrepresentations of the Defendants set forth hereinabove, said Defendants knew and were aware or should have known that ACTOS had been insufficiently tested, and/or had not been tested, that it lacked adequate and/or accurate warnings, and/or that it created a high risk and/or higher than acceptable risk, and/or higher than reported/represented risks, as well as unreasonable, dangerous side effects, including, inter alia, bladder cancer, heart attacks, congestive heart failure and cardiac arrhythmias, as well as other severe and personal injuries which are permanent and lasting in nature.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 160.

161. As a result of the foregoing acts and omissions the Plaintiffs/Decedents requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs/Decedents are informed and believe and further allege that Plaintiffs/Decedents will in the future be required to obtain further medical and/or hospital care, attention, and services.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 161.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs/Decedents for their injuries and which will deter the Defendants and others from like conduct.

ANSWER: Takeda and Eli Lilly admit that Plaintiffs seek judgment and damages, but deny that Plaintiffs are entitled to judgment, damages, or relief of any kind. Takeda and Eli Lilly further deny the remaining allegations of this unnumbered paragraph.

ELEVENTH CAUSE OF ACTION
AGAINST THE DEFENDANTS
FRAUD AND DECEIT

162. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: Takeda and Eli Lilly incorporate by reference the preceding paragraphs of this Answer as if fully set forth herein.

163. Defendants conducted research and used ACTOS as part of their research.

ANSWER: Takeda admits that TPC has researched ACTOS®. Takeda denies the remaining allegations of paragraph 163.

Eli Lilly lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 163.

164. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including, but not limited to, assuring the public, the Plaintiffs/Decedents, their doctors, hospitals, healthcare professionals, and/or the FDA that ACTOS was safe and effective for use.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly deny the remaining allegations of paragraph 164.

165. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiffs/Decedents.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 165.

166. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiffs/Decedents, as well as their respective healthcare providers and/or the FDA.

ANSWER: Takeda and Eli Lilly state that the allegations of paragraph 166 constitute legal conclusions to which no response is required. To the extent that these allegations are construed

as factual allegations directed to Takeda and Eli Lilly, they admit that they complied with their duty under the law at all times. Takeda and Eli Lilly deny the remaining allegations of paragraph 166.

167. The information distributed to the public, the FDA, and the Plaintiffs/Decedents by Defendants, including, but not limited to, reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 167.

168. The information distributed to the public, the FDA, and the Plaintiffs/Decedents by Defendants intentionally included representations that Defendants' drug ACTOS was safe and effective for use.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly deny the remaining allegations of paragraph 168.

169. The information distributed to the public, the FDA, and the Plaintiffs/Decedents, by Defendants intentionally included representations that Defendants' drug ACTOS carried the same risks, hazards, and/or dangers as other alternative medications.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 169.

170. The information distributed to the public, the FDA, and the Plaintiffs/Decedents, by Defendants intentionally included false representations that ACTOS was as potentially injurious to the health and/or safety of its intended use as other alternative medications.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 170.

171. These representations were all false and misleading.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 171.

172. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that ACTOS was not safe.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 172.

173. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiffs/Decedents, regarding the safety of ACTOS, specifically, but not limited to ACTOS not having dangerous and serious health and/or safety concerns.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 173.

174. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and the Plaintiffs/Decedents, regarding the safety of ACTOS.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 174.

175. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiffs/Decedents, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiffs/Decedents, to falsely ensure the quality and fitness for use of ACTOS and induce the public, and/or the Plaintiffs/Decedents to purchase, request, dispense, prescribe, recommend, and/or continue to use ACTOS.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 175.

176. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiffs/Decedents that ACTOS was fit and safe for its intended use.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly deny the remaining allegations of paragraph 176.

177. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiffs/Decedents that ACTOS was fit and safe for use and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other alternative medications.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly deny the remaining allegations of paragraph 177.

178. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiffs/Decedents that ACTOS did not present serious health and/or safety risks.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 178.

179. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiffs/Decedents that ACTOS did not present health and/or safety risks greater than alternative forms of medication.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 179.

180. That these representations and others made by Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 180.

181. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiffs/Decedents, including their respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiffs/Decedents and/or their respective healthcare professionals to rely upon misrepresentations and caused the Plaintiffs/Decedents to purchase, use, rely on, request, dispense, recommend, and/or prescribe ACTOS.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' prescriptions for and purchases and use of ACTOS®. Takeda and Eli Lilly deny the remaining allegations of paragraph 181.

182. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of ACTOS to the public at large, the Plaintiffs/Decedents in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 182.

183. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of ACTOS by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of ACTOS.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 183.

184. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiffs/Decedents, as well as their respective healthcare professionals into a sense of security so that Plaintiffs/Decedents would rely on the representations and purchase, use and rely on ACTOS and/or that their respective healthcare providers would dispense, prescribe, and/or recommend the same.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 184.

185. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiffs/Decedents, as well as their respective healthcare professionals would rely upon the information being disseminated.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 185.

186. Defendants utilized direct to consumer advertising to market, promote, and/or advertise ACTOS.

ANSWER: Takeda and Eli Lilly, on information and belief, admit that, pursuant to approval by the FDA, TPA and TPUSA have marketed ACTOS® for prescription by licensed physicians in the United States, including through direct-to-consumer advertisements. Takeda and Eli Lilly further admit that, pursuant to approval by the FDA, Eli Lilly marketed ACTOS® from 1999 to 2006 for prescription by licensed physicians in the United States. Takeda and Eli Lilly deny the remaining allegations of paragraph 186.

187. That the Plaintiffs/Decedents and/or their respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations and were thereby induced to purchase, use and rely on Defendants' drug ACTOS.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' purchases and use of ACTOS®. Takeda and Eli Lilly deny the remaining allegations of paragraph 187.

188. That at the time the representations were made, the Plaintiffs/Decedents and/or their respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of ACTOS.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 188.

189. That the Plaintiffs/Decedents did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could the Plaintiffs/Decedents with reasonable diligence have discovered the true facts.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly deny the remaining allegations of paragraph 189.

190. That had the Plaintiffs/Decedents known the true facts with respect to the dangerous and serious health and/or safety concerns of ACTOS, Plaintiffs/Decedents would not have purchased, used and/or relied on Defendants' drug ACTOS.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' purchases and use of ACTOS®. Takeda and Eli Lilly deny the remaining allegations of paragraph 190.

191. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiffs/Decedents.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 191.

192. As a result of the foregoing acts and omissions Plaintiffs/Decedents were caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, inter alia, bladder cancer, heart attacks, and cardiac arrhythmias, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 192.

193. As a result of the foregoing acts and omissions the Plaintiffs/Decedents require and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs/Decedents are informed and believe and further allege that Plaintiffs/Decedents will in the future be required to obtain further medical and/or hospital care, attention, and services.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 193.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs/Decedents for their injuries and which will deter the Defendants and others from like conduct.

ANSWER: Takeda and Eli Lilly admit that Plaintiffs seek judgment and damages, but deny that Plaintiffs are entitled to judgment, damages, or relief of any kind. Takeda and Eli Lilly further deny the remaining allegations of this unnumbered paragraph.

TWELFTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
PUNITIVE DAMAGES

194. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: Takeda and Eli Lilly incorporate by reference the preceding paragraphs of this Answer as if fully set forth herein.

195. At all times material hereto, the Defendants knew or should have known that ACTOS was inherently more dangerous with respect to the risk of bladder cancer, heart attacks, congestive heart failure and cardiac arrhythmias.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 195.

196. At all times material hereto, the Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the subject product.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 196.

197. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including the Plaintiffs/Decedents herein, concerning the safety and efficacy of the subject product.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 197.

198. At all times material hereto, the Defendants knew and recklessly disregarded the fact that ACTOS was subject to an increased risk of bladder cancer, heart attacks, congestive heart failure and cardiac arrhythmias with far greater frequency than safer alternative medications.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 198.

199. Notwithstanding the foregoing, the Defendants continued to aggressively market the subject product without disclosing the aforesaid side effects when there were safer alternative medications.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 199.

200. The Defendants knew of the subject product's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiffs/Decedents herein, in conscious and/or negligent disregard of the foreseeable harm.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 200.

201. The Defendants' intentional and/or reckless, fraudulent and malicious failure to disclose information deprived the Plaintiffs/Decedents and their physician of necessary information to enable them to weigh the true risks of using the subject product against its benefits.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 201.

202. As a direct and proximate result of the Defendants' conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiffs/Decedents, the Plaintiffs /Decedents suffered severe injuries as set forth above.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 202.

203. The aforesaid conduct of Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including the Plaintiffs/Decedents herein, thereby entitling the Plaintiffs/Decedents to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 203.

204. The Plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

ANSWER: Takeda and Eli Lilly admit that Plaintiffs seek actual and punitive damages, but deny that Plaintiffs are entitled to damages of any kind. Takeda and Eli Lilly further deny the remaining allegations of paragraph 204.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs/Decedents for their injuries and which will deter the Defendants and others from like conduct.

ANSWER: Takeda and Eli Lilly admit that Plaintiffs seek judgment and damages, but deny that Plaintiffs are entitled to judgment, damages, or relief of any kind. Takeda and Eli Lilly further deny the remaining allegations of this unnumbered paragraph.

THIRTEENTH CAUSE OF ACTION
AGAINST DEFENDANTS
VIOLATION OF CONSUMER PROTECTION STATUTES

205. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: Takeda and Eli Lilly incorporate by reference the preceding paragraphs of this Answer as if fully set forth herein.

206. At all times material hereto, the Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below when it failed to adequately warn consumers and the medical community of the safety risks associated with the ACTOS.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 206.

207. At all times material hereto, the Defendants knew and recklessly disregarded the fact that ACTOS was subject to an increased risk of bladder cancer, heart attacks, congestive heart failure and cardiac arrhythmias with far greater frequency than safer alternative medications.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 207.

208. Notwithstanding the foregoing, the Defendants continued to aggressively market the subject product without disclosing the aforesaid side effects when there were safer alternative medications.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 208.

209. As a direct result of Defendants' deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs/Decedents suffered and will continue to suffer personal injury, economic loss, pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 209.

210. Defendants have engaged, in the State of Florida, in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. §§ 501.201 *et seq*.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 210.

211. Defendants have engaged in the State of South Dakota, in unfair competition or unfair or deceptive acts or practices in violation of S.D. Codified Laws §§ 37-24-1 *et seq*.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 211.

212. Defendants have engaged, in the State of Washington, in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code. §§ 19.86.010 *et seq*.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 212.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs/Decedents for their injuries and which will deter the Defendants and others from like conduct.

ANSWER: Takeda and Eli Lilly admit that Plaintiffs seek judgment and damages, but deny that Plaintiffs are entitled to judgment, damages, or relief of any kind. Takeda and Eli Lilly further deny the remaining allegations of this unnumbered paragraph.

FOURTEENTH CAUSE OF ACTION
AGAINST DEFENDANTS PURSUANT TO
STATE PRODUCTS LIABILITY ACTS OR STATUTES

213. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein

ANSWER: Takeda and Eli Lilly incorporate by reference the preceding paragraphs of this Answer as if fully set forth herein.

214. Defendants were at all times relevant to this suit, and now are, engaged in the business of designing, manufacturing, testing, marketing, and/or placing into the stream of commerce pharmaceuticals for sale to, and use by, members of the public, including the ACTOS at issue in this lawsuit. The ACTOS placed into the stream of commerce by Defendants reached Plaintiffs/Decedents without substantial change and was ingested as directed. The ACTOS was defective and unreasonably dangerous when it entered into the stream of commerce and when used by Plaintiffs/Decedents.

ANSWER: Takeda and Eli Lilly, on information and belief, admit that, pursuant to approval by the FDA, TPC has manufactured ACTOS®, TPA has sold, marketed and distributed ACTOS®, and TPUSA has marketed ACTOS® for prescription by licensed physicians in the United States. Takeda and Eli Lilly further admit that, pursuant to approval by the FDA, Eli Lilly marketed ACTOS® from 1999 to 2006 for prescription by licensed physicians in the United States. Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' receipt and ingestion of ACTOS®. Takeda and Eli Lilly deny the remaining allegations of paragraph 214. Eli Lilly specifically denies any allegation that it designed or manufactured ACTOS®.

215. Plaintiffs hereby set forth that the Defendants are liable to Plaintiffs/Decedents under the Florida Products Liability Act.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 215.

216. Plaintiffs hereby set forth that the Defendants are liable to Plaintiffs/Decedents under the South Dakota Liability Act.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 216.

217. Plaintiffs hereby set forth that the Defendants are liable to Plaintiffs/Decedents under the Washington Products Liability Act.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 217.

218. Defendants are believed to be "manufacturers" and/or "sellers" of ACTOS pursuant to the aforementioned Products Liability Act Statues.

ANSWER: Takeda and Eli Lilly state that the allegations of paragraph 218 constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda and Eli Lilly, Takeda and Eli Lilly, on information and belief, admit that, pursuant to approval by the FDA, TPC manufactures ACTOS® and TPA sells ACTOS® for prescription by licensed physicians in the United States. Takeda and Eli Lilly

deny the remaining allegations of paragraph 218. Eli Lilly specifically denies any allegation that it manufactured ACTOS®.

219. Plaintiffs hereby set forth that the Defendants are liable to Plaintiffs/Decedents under the aforementioned Products Liability Act Statutes:

a. At the time ACTOS left the control of the Defendants it was defective and unreasonably dangerous due to a failure to contain adequate warnings or instructions, or, in the alternative, because it was designed in a defective manner, or, in the alternative, because the product breached an express warranty or failed to conform to other expressed factual representations upon which Plaintiffs/Decedents' physicians justifiably relied, or because it breached an implied warranty, all of which proximately caused the damages for which Plaintiffs/Decedents seek recovery herein;

b. ACTOS was not reasonably safe as designed, taking into account the foreseeable risks involved in its use at the time the product left the possession of the Defendants, and that such risks clearly outweighed the utility of the product or its therapeutic benefits;

c. At the time ACTOS left the control of the Defendants it possessed a dangerous characteristic that may cause damage and it was not reasonably safe due to inadequate or defective warnings or instructions that were known or reasonably scientifically knowable at the time the product left the possession of the Defendants. Specifically, although the Defendants were well aware that ACTOS could potentially cause inter alia, bladder cancer, heart attacks, congestive heart failure and cardiac arrhythmias, warnings of such adverse health conditions were either not included on the package insert for these products or they were not adequate to inform reasonably prudent physicians and consumers. The Defendants failed to use reasonable care to provide an adequate warning of these dangerous characteristics to handlers and users of ACTOS.

d. The Defendants' warnings or instructions were not of a nature that a reasonably prudent drug company in the same or similar circumstances would have provided with respect to the danger. There were no warnings or instructions that communicated sufficient information on the dangers and safe use of the product taking into account the characteristics of the product, and/or the ordinary knowledge common to then physician who prescribes and the consumer who purchases the product, such as the Plaintiffs/Decedents.

e. The ACTOS manufactured and supplied by the Defendants was further defective due to inadequate post-marketing warning or instruction because, after the Defendants knew or should have known of the risks of

injury from ACTOS associated with the long-term use as commonly prescribed, they failed to promptly respond to and adequately warn about inter alia, bladder cancer, heart attacks, congestive heart failure and cardiac arrhythmias;

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 219, including all subparts.

Eli Lilly specifically denies any allegation that it manufactured ACTOS®.

220. The ACTOS at issue is unreasonably dangerous for long-term use in that the risks of developing inter alia, bladder cancer, heart attacks, congestive heart failure and cardiac arrhythmias, among other adverse reactions outweigh the benefits of the drug.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 220.

221. At all times pertinent and material hereto, there existed alternative feasible drugs to provide comparable long-term benefits of ACTOS without the attendant risks of developing inter alia, bladder cancer, heart attacks, congestive heart failure and cardiac arrhythmias, among other adverse reactions.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 221.

222. At all times pertinent and material hereto, Defendants knew that ACTOS was unreasonably dangerous and/or defective as set forth herein.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 222.

223. In the alternative, Defendants should have, at all times pertinent and material hereto, known of the unreasonably dangerous and/or defective characteristics and/or conditions of ACTOS, had it reasonably employed then-existing scientific and/or technical knowledge, reasonable testing, and/or other reasonable and then-accepted methods of quality assurance and/or quality control.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 223.

224. ACTOS manufactured by Defendants is unreasonably dangerous due to an inadequate warning that, at the time the drug left Defendants' control, possessed a characteristic that might cause damage or injury to patients including Plaintiffs/Decedents, and yet Defendants failed to use reasonable care to provide an adequate warning of such characteristics and/or dangers to prescribing physicians and/or users of the drug.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 224. Eli Lilly specifically denies any allegation that it manufactured ACTOS®.

225. In addition, and in the alternative, the ACTOS manufactured by Defendants is unreasonably dangerous in design, in that, at the time the drug left the Defendants' control, there existed, upon information and belief, an alternative design for the drug that was capable of preventing Plaintiffs/Decedents' injuries, and the likelihood of causing the Plaintiffs/Decedents' injuries and the gravity of that harm outweighed the burden (if any) on Defendants in adopting such alternative design and the adverse effect (if any) on the utility of the drug.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 225. Eli Lilly specifically denies any allegation that it designed or manufactured ACTOS®.

226. The Defendants knew or in light of reasonably available scientific knowledge should have known about the danger that caused the injuries for which Plaintiffs/Decedents seek recovery. A reasonably competent physician who prescribed ACTOS and reasonably competent Plaintiffs/Decedents who consumed ACTOS would not realize its dangerous condition.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' prescriptions for and use of ACTOS®. Takeda and Eli Lilly deny the remaining allegations of paragraph 226.

227. The reasonably foreseeable use of ACTOS, that is ingestion for the treatment of Diabetes in patients, such as Plaintiffs/Decedents, involved substantial dangers not readily recognizable by the ordinary physician who prescribed ACTOS or the patients, like Plaintiffs/Decedents, who consumed ACTOS.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' use of ACTOS®. Takeda and Eli Lilly deny the remaining allegations of paragraph 227.

228. Defendants failed to provide adequate warnings based on what they knew or should have known about the adverse effects of ACTOS.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 228.

229. Plaintiffs/Decedents and their physicians did not know, nor had reason to know, at the time of the use of ACTOS, or at any time prior to its use, of the existence of the above-described defects and inadequate warnings.

ANSWER: Takeda and Eli Lilly admit that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' use of ACTOS®. Takeda and Eli Lilly deny the remaining allegations of paragraph 229.

230. These defects caused serious injuries to Plaintiffs/Decedents when the product was used in its intended and foreseeable manner, and in the manner recommended by Defendants or in a non-intended manner that was reasonably foreseeable.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' use of ACTOS®. Takeda and Eli Lilly deny the remaining allegations of paragraph 230.

231. Defendants are therefore liable to Plaintiffs/Decedents for any and all damages arising from injuries including, inter alia, bladder cancer, heart attacks, congestive heart failure and cardiac arrhythmias and other adverse reactions, and/or other purchase and/or use of the drug.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' purchases and use of ACTOS®. Takeda and Eli Lilly deny the remaining allegations of paragraph 231.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs/Decedents for their injuries and which will deter the Defendants and others from like conduct.

ANSWER: Takeda and Eli Lilly admit that Plaintiffs seek judgment and damages, but deny that Plaintiffs are entitled to judgment, damages, or relief of any kind. Takeda and Eli Lilly further deny the remaining allegations of this unnumbered paragraph.

FIFTEENTH CAUSE OF ACTION
AGAINST THE DEFENDANTS
LOSS OF CONSORTIUM

232. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: Takeda and Eli Lilly incorporate by reference the preceding paragraphs of this Answer as if fully set forth herein.

233. Plaintiffs incorporate by reference the paragraphs above, as though fully set forth herein.

ANSWER: Takeda and Eli Lilly incorporate by reference the preceding paragraphs of this Answer as if fully set forth herein.

234. As a direct and proximate result of the foregoing, Plaintiffs were deprived of the comfort and enjoyment of the services and society of their spouses, and have suffered and will continue to suffer economic loss, and have otherwise been emotionally and economically injured. Plaintiffs' injuries and damages are permanent and will continue into the future. Plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' marital status. Takeda and Eli Lilly admit that Plaintiffs seek damages, but deny that Plaintiffs are entitled to damages of any kind. Takeda and Eli Lilly further deny the remaining allegations of paragraph 234.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs/Decedents for their injuries and which will deter the Defendants and others from like conduct

ANSWER: Takeda and Eli Lilly admit that Plaintiffs seek judgment and damages, but deny that Plaintiffs are entitled to judgment, damages, or relief of any kind. Takeda and Eli Lilly further deny the remaining allegations of this unnumbered paragraph.

SIXTEENTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
REDHIBITION

235. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: Takeda and Eli Lilly incorporate by reference the preceding paragraphs of this Answer as if fully set forth herein.

236. ACTOS has serious health and/or safety concerns with side effects so dangerous, buyers would not have purchased, used and relied on ACTOS for treatment.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 236.

237. Defendants sold and promoted the subject product, which Defendants placed into the stream of commerce. The seller warrants the buyer against redhibitory defects, or vices, in the thing sold. The subject product sold and promoted by the Defendants, possesses a redhibitory defect because it was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which renders the subject product useless or so dangerous that it must be presumed that a buyer would not have had used ACTOS had he known of the defects. Plaintiffs/Decedents are entitled to obtain a rescission of the sale of the subject product.

ANSWER: Takeda and Eli Lilly, on information and belief, admit that, pursuant to approval by the FDA, TPA has sold and marketed ACTOS® and TPUSA has marketed ACTOS® for prescription by licensed physicians in the United States. Takeda and Eli Lilly further admit that, pursuant to approval by the FDA, Eli Lilly marketed ACTOS® from 1999 to 2006 for prescription by licensed physicians in the United States. Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' purchases of ACTOS®. Takeda and Eli Lilly deny the remaining allegations of paragraph 237. Eli Lilly specifically denies any allegation that it is the manufacturer of ACTOS®.

238. The subject product alternatively possess a redhibitory defect because the subject product was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which diminishes the value of the subject product

so that it must be presumed that a buyer would still have purchased it but for a lesser price. In this instance, Plaintiffs/Decedents are entitled to a reduction of the purchase price.

ANSWER: Takeda and Eli Lilly lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' purchases of ACTOS®. Takeda and Eli Lilly deny the remaining allegations of paragraph 238. Eli Lilly specifically denies any allegation that it is the manufacturer of ACTOS®.

239. Defendants are liable as bad faith sellers for selling a defective product with knowledge of the defect and thus are liable to Plaintiffs/Decedents for the price of the subject product, with interest from the purchase date, as well as reasonable expenses occasioned by the sale of the subject product, and attorneys' fees. As the manufacturer of the subject product, Defendants are deemed to know that the subject product possessed a redhibitory defect.

ANSWER: Takeda and Eli Lilly deny the allegations of paragraph 239. Eli Lilly specifically denies any allegation that it is the manufacturer of ACTOS®.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs/Decedents for their injuries and which will deter the Defendants and others from like conduct.

ANSWER: Takeda and Eli Lilly admit that Plaintiffs seek judgment and damages, but deny that Plaintiffs are entitled to judgment, damages, or relief of any kind. Takeda and Eli Lilly further deny the remaining allegations of this unnumbered paragraph.

PLAINTIFFS' PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiffs for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiffs, health care costs, medical monitoring, together with interest and costs as provided by law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct;

3. Awarding Plaintiffs reasonable attorneys' fees;

4. Awarding Plaintiffs the costs of these proceedings; and

5. Such other and further relief as this Court deems just and proper.

ANSWER: Takeda and Eli Lilly admit that Plaintiffs seek judgment, actual and punitive damages, and other relief, but deny that Plaintiffs are entitled to judgment, damages, or relief of any kind. Takeda and Eli Lilly further deny the remaining allegations of Plaintiffs' Prayer for Relief.

GENERAL DENIAL AND SEPARATE OR AFFIRMATIVE DEFENSES OF TAKEDA AND ELI LILLY

Takeda and Eli Lilly specifically deny those allegations contained in the Complaint that are not expressly admitted in their Answer. Discovery and investigation may reveal that one or more of the following additional defenses should be available to Takeda or Eli Lilly in this matter. Takeda and Eli Lilly accordingly reserve the right to assert these separate and additional defenses. Upon completion of discovery, if the facts warrant, Takeda or Eli Lilly may withdraw any of these additional defenses as may be appropriate. Takeda and Eli Lilly further reserve the right to amend their Answer and defenses, and to assert additional defenses and other claims, as this matter proceeds.

Further answering, and by way of additional defense, Takeda and Eli Lilly state as follows:

1. Plaintiffs' Complaint against Takeda and Eli Lilly fails to state a claim upon which relief may be granted.

2. Plaintiffs' alleged injuries were proximately caused by circumstances, events, or persons over whom Takeda and Eli Lilly had no authority or control and for which Takeda and Eli Lilly are not answerable in damages to Plaintiffs.

3. Plaintiffs assumed the risks, if any, inherent in the use and continued use of ACTOS®.

4. To the extent Plaintiffs' claims were caused by the actions, omissions, or products of persons or entities over whom Takeda and/or Eli Lilly have no dominion, authority, or control, Takeda and Eli Lilly are entitled to have their liability to the Plaintiffs, if any, reduced as a result of the fault or negligence of said persons or entities, pursuant to governing law.

5. Plaintiffs' recovery is barred and/or should be reduced because of Plaintiffs' contributory negligence or fault and/or comparative negligence.

6. The alleged injuries sustained by Plaintiffs, if any, were caused, in whole or in part, by Plaintiffs' pre-existing physical, medical, and/or physiological conditions, for which neither Takeda nor Eli Lilly has legal responsibility.

7. Plaintiffs' alleged injuries, if related to Plaintiffs' use of ACTOS®, were caused by an unforeseeable material and substantial alteration, change, improper handling, or misuse of the product after it left the control of Takeda and/or Eli Lilly.

8. The New Drug Application for ACTOS® was approved by the FDA under the applicable statute, 21 U.S.C. § 301 *et seq*., and regulations promulgated thereunder. Compliance with such statutes and regulations by Takeda demonstrates that ACTOS® was safe and effective and not unreasonably dangerous and, further, preempts and bars Plaintiffs' claims against Takeda and Eli Lilly. Compliance with such statutes and regulations also demonstrates that due care was exercised with respect to the design, manufacture, testing, marketing and sale of this prescription drug, and that it was neither defective nor unreasonably dangerous.

9. Plaintiffs' claims are preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution because of the pervasive federal regulation

of prescription drug manufacturing, testing, marketing, and labeling, and the FDA's specific determinations regarding ACTOS® and other drugs in its class.

10. All labeling for ACTOS® has been approved by the FDA under the applicable statute, 21 U.S.C. § 301 *et seq*., and regulations promulgated thereunder. Plaintiffs' claims are preempted by federal law pursuant to the Supremacy Clause of the United States Constitution to the extent Plaintiffs assert that state law required changes to the FDA-approved labeling that the FDA itself would not have approved. Plaintiffs' claims also are preempted by federal law pursuant to the Supremacy Clause of the United States Constitution because they would obstruct the federal regulation of drug labeling and frustrate the achievement of congressional objectives.

11. To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

12. Plaintiffs' claims against Takeda and Eli Lilly are barred as a matter of law pursuant to relevant provisions of the Restatement (Third) of Torts and the Restatement (Second) of Torts, including, but not limited, to Section 402A, comment k.

13. Plaintiffs' claims are barred, in whole or in part, because the pharmaceutical product at issue provides net benefits for a class of patients within the meaning of Restatement (Third) of Torts: Products Liability § 6 cmt. f.

14. Takeda and Eli Lilly give notice that, to the extent that the sophisticated purchaser doctrine is applicable to any of the allegations in the Complaint, Takeda and Eli Lilly intend to rely upon same in defense of this action.

15. Plaintiffs' claims are barred in whole or in part by the learned intermediary doctrine. Any warnings which were given were transmitted to the prescribing health care provider and

Takeda and Eli Lilly's only obligation is to warn the prescribing health care provider, which obligation was fulfilled.

16. Plaintiffs' Complaint fails to state a claim upon which relief can be granted against Takeda and Eli Lilly, in that the methods, standards, and techniques utilized with respect to the design, manufacture, marketing, and sale of ACTOS®, including adequate warnings and instructions with respect to the product's use included in the product's package insert and other literature, conformed to the applicable state of the art, and the applicable standard of care based upon available medical and scientific knowledge.

17. Plaintiffs' claims are barred because ACTOS® was neither defective nor unreasonably dangerous in its design, manufacture or marketing and was reasonably safe and reasonably fit for its intended uses, thereby barring Plaintiffs' recovery.

18. The warnings and instructions accompanying ACTOS® at the time of the occurrence or injuries alleged by Plaintiffs were legally adequate warnings and instructions.

19. Plaintiffs' claims are barred, in whole or in part, by prescription, preemption, and/or the applicable statutes of limitations and/or repose.

20. Plaintiffs' claims against Takeda and Eli Lilly are barred, in whole or in part, by laches, waiver, and/or estoppel.

21. Plaintiffs' claims are barred, in whole or in part, by Plaintiffs' failure to mitigate alleged damages.

22. The injuries and damages claimed by Plaintiffs, if any, resulted from an intervening or superseding cause and/or causes, and any act or omission on the part of Takeda and/or Eli Lilly was not the proximate and/or competent producing cause of such alleged injuries and damages.

23. Any claims by Plaintiffs relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First and Fourteenth Amendment rights to petition the government.

24. The alleged injuries and damages, if any, were the result of unavoidable circumstances that could not have been prevented by any person, including Takeda and Eli Lilly.

25. Plaintiffs' claims are barred because the benefits of ACTOS® outweigh the risks, if any, that might be associated with the product.

26. Plaintiffs' Complaint fails to state a claim upon which relief can be granted as to costs, attorney's fees, expert fees, expenses, pre-judgment interest, post-judgment interest, refund, rescission, unjust enrichment, disgorgement, or restitution.

27. Plaintiffs' claims are barred in whole or in part because the commercial speech relating to ACTOS® was not false or misleading and is protected under the First Amendment to the United States Constitution and the applicable state constitutions.

28. Plaintiffs' claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under law with determining the content of warnings and labeling for prescription drugs.

29. Plaintiffs cannot state a claim with regard to warnings and labeling for prescription drugs because the remedy sought by Plaintiffs is subject to the exclusive regulation of the FDA.

30. This Court should abstain from adjudicating Plaintiffs' claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription drug labeling by the FDA.

31. If ACTOS® was unsafe (which Takeda and Eli Lilly deny), Plaintiffs' claims are barred because ACTOS® was unavoidably unsafe.

32. Upon information and belief, each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified in whole or in part from collateral sources.

33. To the extent that Plaintiffs' Complaint seeks recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action under applicable law.

34. To the extent that Plaintiffs' claims have been settled or Plaintiffs will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, the liability of Takeda and Eli Lilly, if any, should be reduced accordingly.

35. Plaintiffs' claims may be barred, in whole or in part, due to res judicata, collateral estoppels, or by release of claims.

36. Plaintiffs' Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

37. Plaintiffs' Complaint fails to state a claim for fraud, misrepresentation, or suppression, and fails to allege the circumstances constituting fraud with the particularity required by the Federal Rules of Civil Procedure.

38. Plaintiffs did not detrimentally rely on any labeling, warnings, or information concerning ACTOS®.

39. Applicable law does not recognize a post-sale duty to warn in the present circumstances. Accordingly, the Complaint fails to state a claim upon which relief may be granted for inadequate post-sale marketing or post-sale duty to warn.

40. Plaintiffs' alleged injuries and damages, if any, were the result of an idiosyncratic reaction which Takeda and Eli Lilly could not reasonably foresee.

41. Plaintiffs, or Plaintiffs' physicians, were aware or should have been aware of any potential hazards reported to be associated with the use of ACTOS® and appreciated or should have appreciated these potential hazards based, in part, on the directions, information, and warnings provided by Takeda, Eli Lilly, and others generally available in the medical and scientific literature. Therefore, Takeda and Eli Lilly had no duty to warn of any alleged danger or defect.

42. Plaintiffs are barred from recovering any damages by virtue of the fact that there was no practical or technically feasible alternative design or formulation that would have prevented the harm alleged by the Plaintiffs without substantially impairing the usefulness or intended purpose of the product.

43. Plaintiffs' claims are barred because ACTOS® was consistent with and exceeded consumer expectations.

44. Plaintiffs' claims for breach of warranty are barred because Plaintiffs failed to give timely notice of any alleged failure.

45. Neither Takeda nor Eli Lilly sold or distributed ACTOS® directly to Plaintiffs, and Plaintiffs did not receive or rely upon any representations or warranties as alleged in the Complaint. Plaintiffs' claims are therefore barred by lack of privity.

46. Any warranties made by Takeda or Eli Lilly to Plaintiffs were disclaimed.

47. Plaintiffs' claims for breach of warranty, express or implied are barred by the applicable provisions of the applicable state Uniform Commercial Codes.

48. Any claim for breach of express warranty must fail because Plaintiffs failed to allege any representation about the product at issue giving rise to an express warranty.

49. Any claim for breach of implied warranty fails because the product at issue was used for its ordinary purpose.

50. Any claim for breach of warranty fails because Plaintiffs failed to satisfy all conditions precedent or subsequent to the enforcement of such warranty.

51. Plaintiffs' claims purportedly asserted under statutes and regulations relating to prescription drugs fail, in whole or in part, because these statutes and regulations do not contain or create any private cause of action.

52. Takeda and Eli Lilly had a good faith belief in the lawfulness of their actions.

53. Plaintiffs' Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages.

54. Any award of punitive or exemplary damages is barred to the extent that it is inconsistent with the standards and limitations set forth in *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and *Exxon Shipping Co. v. Baker*, 128 S. Ct. 2605 (2008). Permitting recovery of punitive or exemplary damages in this action would contravene Takeda's and Eli Lilly's rights as reserved by the Fifth, Seventh, Eighth, and Fourteenth Amendments to the United States Constitution and other provisions of the United States Constitution and the applicable state constitutions.

55. Unless Takeda's and Eli Lilly's liability for punitive damages and the appropriate amount of punitive damages are required to be established by clear and convincing evidence, any award of punitive damages would violate Takeda's and Eli Lilly's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and the applicable state constitutions, and also would be improper under the applicable state common law and public policies.

56. Plaintiffs' claim for punitive damages against Takeda and Eli Lilly cannot be maintained, because an award of punitive damages would be void for vagueness, both facially and as applied. Among other deficiencies, there is an absence of adequate notice of what conduct is subject to punishment; an absence of adequate notice of what punishment may be imposed; an absence of a predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount, on the amount of punitive damages that a jury may impose; a risk that punitive damages will be imposed retrospectively based on conduct that was not deemed punishable at the time the conduct occurred; and it would permit and encourage arbitrary and discriminatory enforcement, all in violation of the due process clause of the Fourteenth Amendment to the United States Constitution, the applicable state constitutions, and applicable state common law and public policies.

57. Plaintiffs' claim for punitive damages against Takeda and Eli Lilly cannot be maintained because any award of punitive damages would be by a jury that: (1) is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive damages award; (2) is not adequately instructed on the limits on punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including the residence, wealth, and corporate status of Takeda and/or Eli Lilly; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; and (5) is not subject to adequate trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of objective

standards. Any such verdict would violate Takeda's and Eli Lilly's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and the applicable state constitutions, and also would be improper under applicable state common law and public policies.

58. To the extent that the applicable state law permits punishment to be measured by the net worth or financial status of Takeda and/or Eli Lilly and imposes greater punishment on defendants with larger net worth, such an award would be unconstitutional because it permits arbitrary, capricious and fundamentally unfair punishments, allows bias and prejudice to infect verdicts imposing punishment, and allows dissimilar treatment of similarly situated defendants, in violation of the due process and equal protection provisions of the Fourteenth Amendment to the United States Constitution, the Commerce Clause of the United States Constitution, and the applicable state constitutions.

59. With respect to Plaintiffs' demand for punitive or exemplary damages, Takeda and Eli Lilly specifically incorporate by reference any and all standards or limitations regarding the determination or enforceability of punitive or exemplary damages awards under federal law and the applicable state law.

60. No act or omission of Takeda or Eli Lilly was willful, unconscionable, oppressive, fraudulent, wanton, malicious, reckless, intentional, or with actual malice, with reckless disregard for the safety of Plaintiffs or with conscious disregard and indifference to the rights, safety and welfare of Plaintiffs, and therefore Plaintiffs' Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages.

61. Plaintiffs' Complaint seeks damages in excess of those permitted by law. Takeda and Eli Lilly assert any statutory or judicial protection from punitive or exemplary damages which is available under the applicable law, and any award of punitive or exemplary damages is barred.

62. This Court is not the proper venue for the adjudication of Plaintiffs' claims, and at the appropriate time, the Court should transfer the case to the proper venue.

63. Takeda and Eli Lilly adopt and incorporate by reference herein any affirmative defenses that may be raised by any other Defendant who is in or may be joined to this action.

64. Takeda and Eli Lilly are entitled to the benefit of all defenses and presumptions provided by the procedural and substantive law of state and federal law.

65. Takeda and Eli Lilly reserve the right to modify, clarify, amend, or supplement these separate or affirmative defenses as discovery proceeds in this case.

ADDITIONAL SEPARATE OR AFFIRMATIVE DEFENSES AS TO FLORIDA PLAINTIFFS

66. Upon information and belief, each economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified in whole or in part by collateral sources. Plaintiffs' damages shall be reduced by the total of all amounts which have been paid for the benefit of Plaintiffs, or which are otherwise available to Plaintiffs, from all collateral sources, in accordance with Florida Statute Section 768.76.

67. To the extent Plaintiffs' claims were caused by the actions, omissions, or products of persons or entities over whom Takeda and Eli Lilly have no dominion, authority, or control, Takeda and Eli Lilly are entitled to have their liability to the Plaintiffs, if any, reduced as a result of the fault or negligence of said persons or entities, pursuant to governing law, including but not limited to the provisions of section 768.81, Florida Statutes. To the extent any recovery is permitted in this case, pursuant to sections 768.31 and 768.81, Florida Statutes, judgment must

be entered on the basis of Takeda and Eli Lilly's percentage of fault, taking into account the percentage of fault attributable to all other persons, whether or not a party hereto, and not on the basis of joint and several liability. The persons or entities referred to in this paragraph that are presently unknown to Takeda and Eli Lilly will be identified in a timely manner consistent with *Nash v. Wells Fargo*, 678 So. 2d 1262 (Fla. 1996).

68. Plaintiffs' claims for breach of warranty, express or implied are barred by Florida's Uniform Commercial Code. Takeda and Eli Lilly not a seller as defined by section 672.103, Florida Statutes.

69. If Plaintiffs sustained any injury, which is denied, said injuries and expenses were proximately caused, in whole or in part, by Plaintiffs and/or persons other than Takeda and Eli Lilly, over whom Takeda and Eli Lilly had no supervision or control, and for whose actions and omissions Takeda and Eli Lilly has no legal responsibility. Plaintiffs' recovery, if any, should be barred, reduced, or apportioned in accordance with Florida Statute sections 768.81 and 768.31.

70. To the extent that Plaintiffs have received payments and/or have delivered or will deliver a release or covenant not to sue any person, firm or corporation in full or partial satisfaction of the damages sued for, Takeda and Eli Lilly are entitled to a set-off of such amount from the amount of any judgment to which Plaintiffs would otherwise be entitled, in accordance with Florida Statute Section 768.041.

71. Plaintiffs' claim for punitive damages is subject to all defenses, conditions and limitations set forth in Florida Statute Section 768.73.

72. In accordance with Florida Statute Section 768.78, Takeda and Eli Lilly assert their right to have any award of judgment made payable in accordance with the alternative methods of payment of damages awards provision therein.

ADDITIONAL SEPARATE OR AFFIRMATIVE DEFENSES AS TO WASHINGTON PLAINTIFFS

73. Pursuant to Washington RCW § 7.72.030, ACTOS® was reasonably safe.

74. Pursuant to Washington RCW § 7.72.050, ACTOS® was produced within industry custom, nongovernmental standards, legislative regulatory and administrative regulatory standards.

SEPARATE OR AFFIRMATIVE DEFENSES OF ELI LILLY

1. Plaintiffs' claims against Eli Lilly are barred and/or preempted by federal law because at no time did Eli Lilly have authority to revise or modify the FDA-approved labeling for ACTOS®.

2. Plaintiffs' claims against Eli Lilly are barred in whole or in part because Eli Lilly was not involved with the co-promotion of ACTOS® in the United States after 2006.

3. Discovery or investigation may reveal that some or all of the claims alleged by Plaintiffs is barred by the doctrines of accord and satisfaction.

JURY DEMAND

Takeda and Eli Lilly hereby demand a trial by jury by the maximum number of jurors permitted by law on all issues so triable.

PRAYER

WHEREFORE, having answered, Takeda and Eli Lilly request that this Court enter judgment in their favor and against Plaintiffs on all counts and allegations of the Complaint and that the Court award Takeda and Eli Lilly their costs and such other relief as it deems just and proper.

DATED: June 19, 2013

Respectfully submitted,

By: */s/ Jaimme A. Collins*

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CERTIFICATE OF SERVICE

I hereby certify that on June 19, 2013, I electronically filed the foregoing Defendants' Answer and Separate or Affirmative Defenses to Plaintiffs' Complaint with the Clerk of Court by using the CM/ECF system, which will send a notice of electronic filing to all parties of record by operation of the Court's electronic filing system.

/s/ Jaimme A. Collins
Jaimme A. Collins